contacting the container of liquid for maintaining the container in fixed position with respect to the housing.

14. The syringe of claim 12 wherein the engaging means comprises a pair of opposed edges situated on opposite sides of the plunger rod so as to prevent movement of the plunger rod toward the housing proximal end.

15. The improvement of claim 14 wherein the hollow cap further comprises a flexible member projecting outward from the cap and the housing further comprises a grooved interior surface, said flexible member engaging said grooved interior surface of the housing such that the calibrated relative adjustment causes sensible movement of the flexible member.

16. The syringe of claim 15 wherein the distal end facing surface comprises the distal end of the cap, and the stop comprises a land within the housing situated to contact the distal end of the cap so that a proximal portion of the cap remains projecting from the proximal end of the housing.

17. The syringe of claim 12 wherein the engaging means comprises a pair of opposed edges situated on opposite sides of the plunger rod so as to prevent movement of the plunger rod toward the housing proximal end.

* * * * *

US005549575A

United States Patent [19]

Giambattista et al.

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[45] Date of Patent: Aug. 27, 1996

[54] **CARTRIDGE RETAINER ASSEMBLY FOR MEDICATION DELIVERY PEN**

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[73] Assignee: Becton Dickinson and Company, Franklin Lakes, N.J.

[21] Appl. No.: 304,953

[22] Filed: Sep. 13, 1994

[51] Int. Cl.[6] A61M 5/00

[52] U.S. Cl. 604/232; 604/206; 604/241

[58] Field of Search 604/232, 234, 604/206-211, 240-243, 181, 187, 199-201, 71, 72, 131-136, 139, 218, 905

[56] References Cited

U.S. PATENT DOCUMENTS

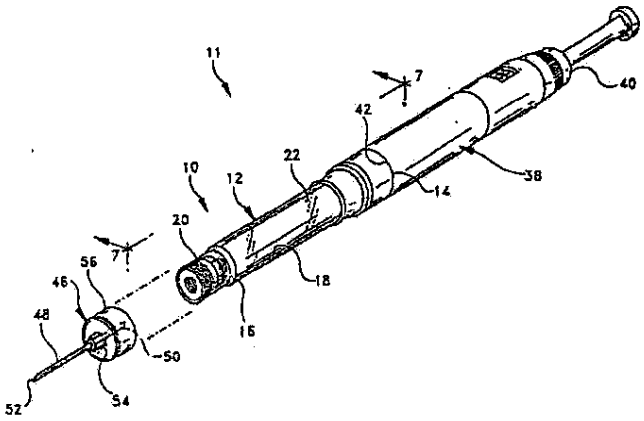
4,973,318	11/1990	Holm et al.	604/208
5,041,088	8/1991	Ritson et al.	604/135
5,085,641	2/1992	Sarnoff et al.	604/135
5,281,198	1/1994	Haber et al.	604/232
5,360,410	11/1994	Wacks	604/205

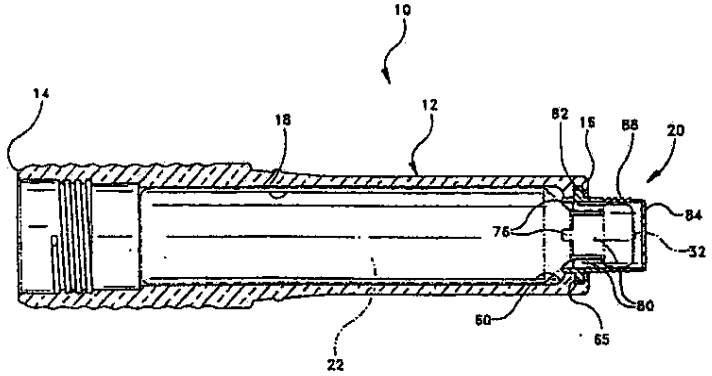
Primary Examiner—John D. Yasko
Assistant Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Alan W. Fiedler

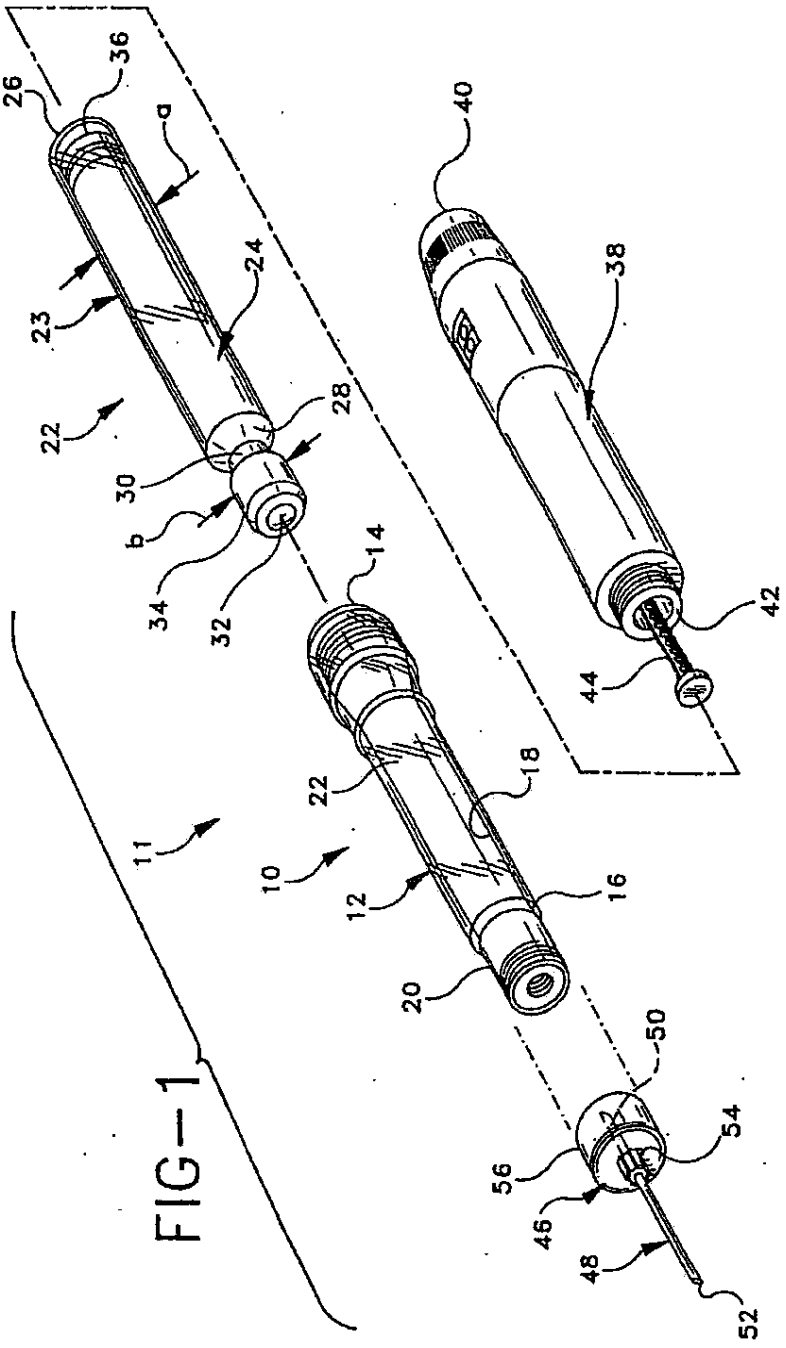
[57] ABSTRACT

A cartridge retainer assembly is provided for a medication delivery pen. The cartridge retainer assembly includes a generally tubular body for receiving, supporting and accurately positioning the body and shoulder portions of a cartridge of medication. A needle mounting collar is floatably mounted to the body of the cartridge retainer assembly for receiving the neck, rubber septum and crimped metallic sleeve of the cartridge. The needle mounting collar will float into a position which compensates for eccentricities and dimensional variations of the cartridge.

9 Claims, 5 Drawing Sheets



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FIG—1

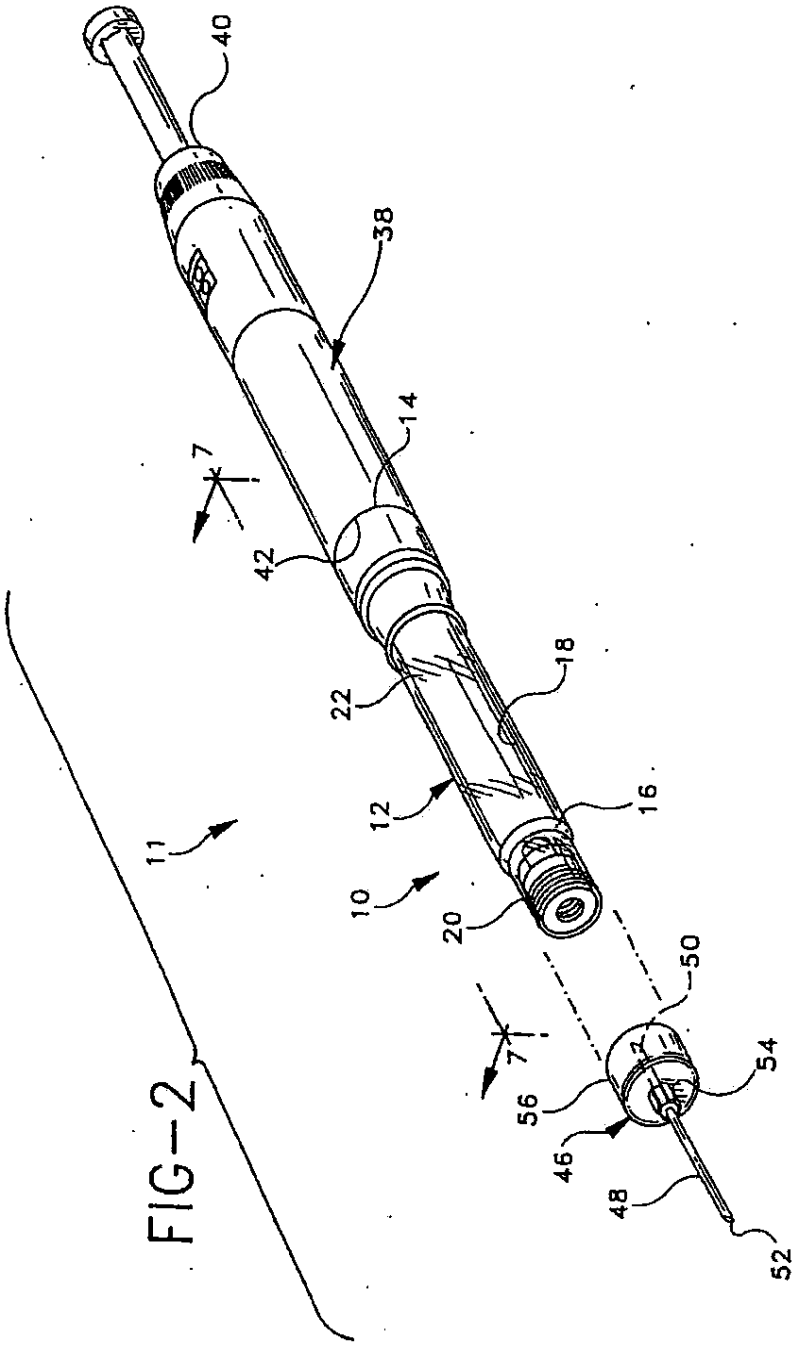

FIG-2

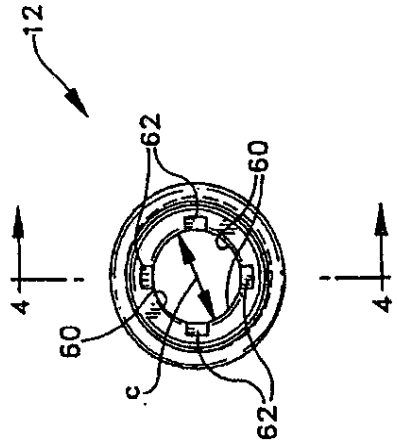

FIG-3

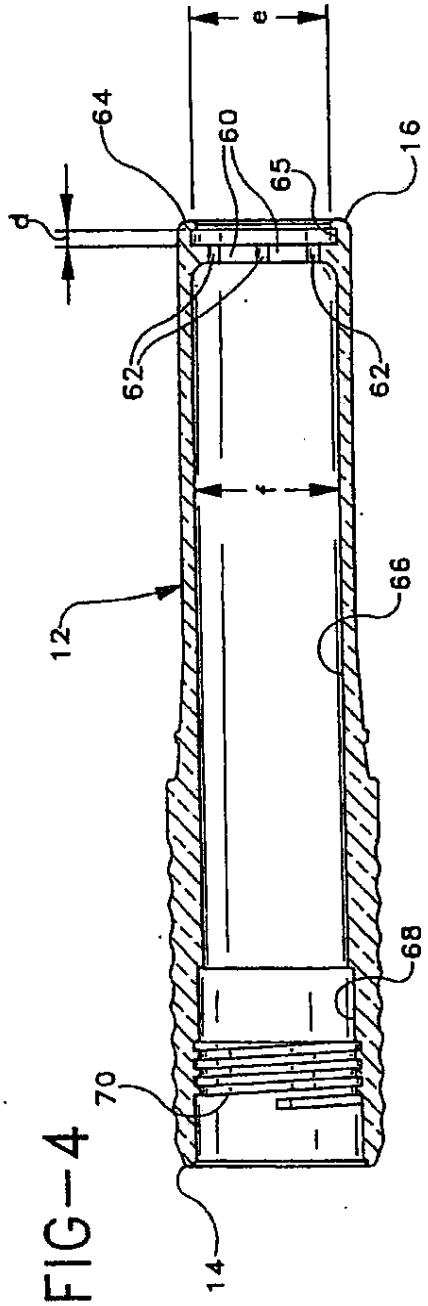

FIG-4

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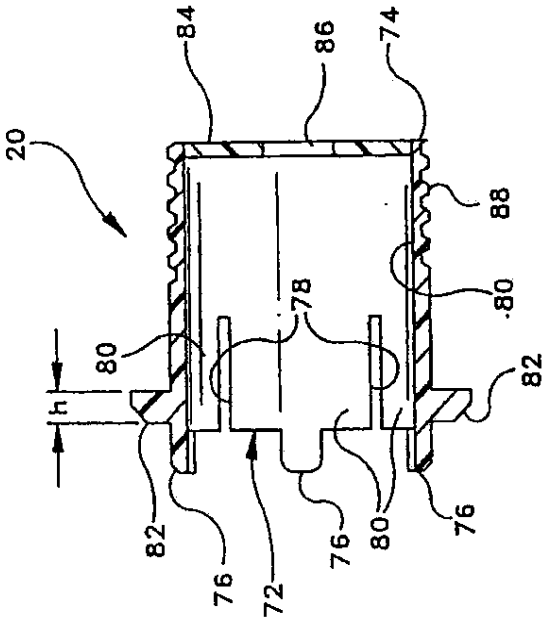
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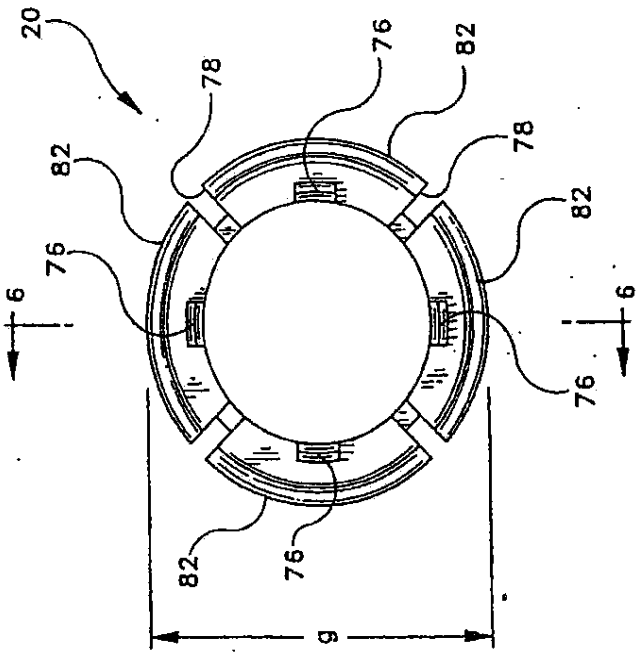
FIG-5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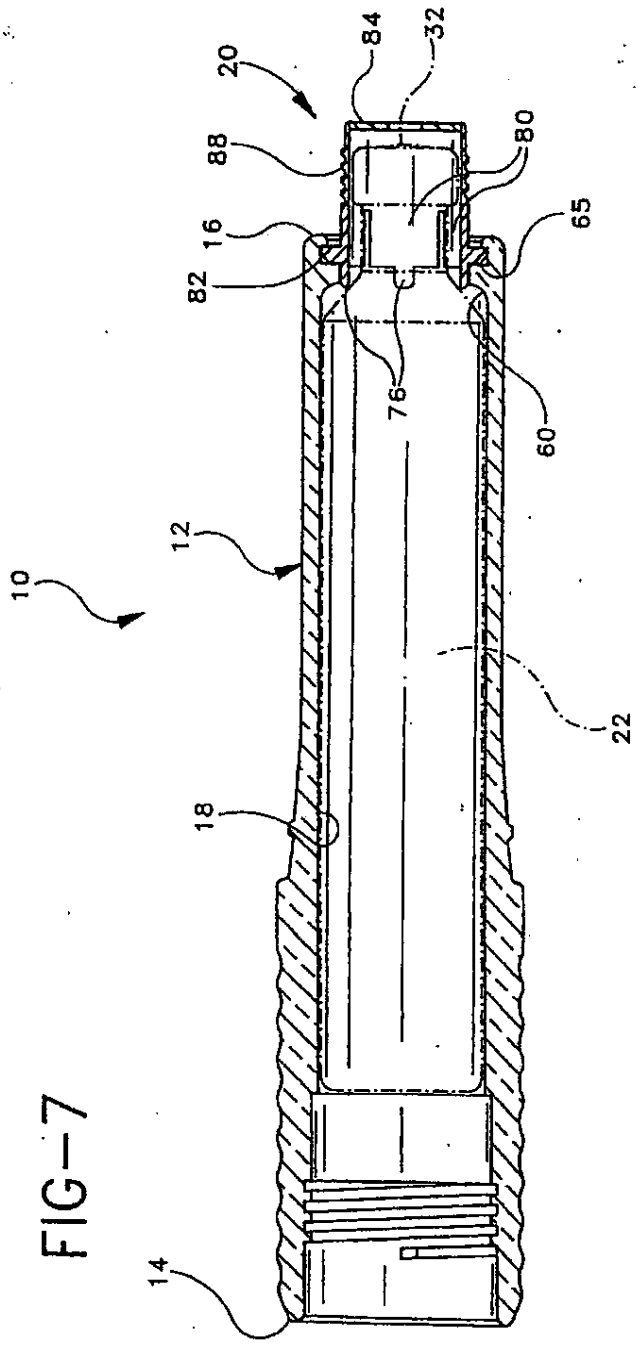

FIG—7

CARTRIDGE RETAINER ASSEMBLY FOR MEDICATION DELIVERY PEN

BACKGROUND OF THE INVENTION

1. Field of the Invention

The subject invention relates to the portion of a medication delivery pen that retains the cartridge of medication.

2. Description of the Prior Art

Medication delivery pens are hypodermic syringes that are used for self-injection of precisely measured doses of medication. Pens are widely used, for example, by diabetics to dispense insulin.

The typical prior art medication delivery pen includes a cartridge which contains a volume of liquid medication sufficient for several doses. The prior art cartridge includes an elongated generally tubular glass vial having an open proximal end and an opposed open distal end. The vial includes a large diameter barrel extending distally from the open proximal end to an inwardly tapering shoulder between the two ends. A short small diameter neck extends from the shoulder to the open distal end. The neck of the prior art vial has an annular rim projecting outwardly around the extreme distal end.

The prior art cartridge further includes a pierceable rubber septum which extends across the open distal end of the prior art vial, and is securely held in position by a metallic sleeve that is crimped to the annular rim on the tubular neck. The vial of the prior art cartridge is filled with liquid medication, and a rubber stopper is inserted into the open proximal end of the vial for sliding fluid-tight engagement with interior walls of the barrel.

The prior art medication delivery pen includes a unitarily molded cartridge retainer with opposed proximal and distal ends. A large diameter tubular body extends distally from the proximal end and is dimensioned for receiving the barrel of the vial. A short smaller diameter tubular neck is disposed distally of the body and is dimensioned for tightly engaging the tubular neck of the vial and the metallic sleeve crimped thereon so as to support and position the entire cartridge. Exterior regions at the extreme distal end of the tubular neck are formed with an array of threads for threadedly receiving the mounting cap of a needle assembly.

The prior art medication delivery pen further includes a dosing apparatus that is engaged with the proximal end of the cartridge retainer. The prior art dosing apparatus includes a plunger for engaging the rubber stopper of the cartridge, dose setting structure for selecting the longitudinal distance through which the plunger will move, and dispensing means for driving the plunger the selected distance. The prior art dosing apparatus may be permanently connected to prior art cartridge retainer with the cartridge therein. This type of prior art pen is used until the medication is exhausted and then the entire pen is discarded. Other prior art medication delivery pens may have the dosing apparatus removably connected to the cartridge retainer so that at least portions of the pen may be reused when the medication in the cartridge is exhausted.

Prior art needle assemblies for medication delivery pens are safely sealed in packages. A needle assembly is accessed immediately prior to an injection, and is discarded immediately after the injection. The prior art needle assembly for medication delivery pens includes an elongate needle cannula having opposed proximal and distal points and a lumen extending therethrough. A plastic cork is adhered to an intermediate position along the needle cannula and in turn is rigidly connected to an end wall of a cylindrical cap. The cylindrical wall of the cap surrounds the proximal point on the needle cannula and includes an array of internal threads for engaging the external threads on the neck of the prior art cartridge retainer.

The prior art medication delivery pen may be used by opening the sealed needle assembly and urging the cap over the neck of the vial retainer sufficiently for the proximal point of the needle cannula to pierce the rubber septum of the prior art cartridge. The cap is then rotated to threadedly engage the neck of the prior art cartridge retainer. The user will then manipulate the dosing apparatus to select an appropriate dose. A protective shield over the distal end of the needle cannula is then removed, and the distal point of the needle cannula is injected. The user then actuates the dispensing means of the prior art dosing apparatus to urge the stopper of the cartridge distally and to deliver medication through the lumen of the needle cannula. The needle is then withdrawn, and the needle assembly is separated from the cartridge retainer and safely discarded. The rubber septum of the cartridge will reseal itself, and may be pierced again for a subsequent administration of medication. This process may be carried out repeatedly until all of the medication in the cartridge has been used.

The neck at the distal end of the prior art unitarily molded cartridge retainer has been precisely formed to closely engage, support and position the entire cartridge. However, cartridges are subject to a considerable range of dimensional variations and a considerable degree of eccentricity. These dimensional variations and eccentricities may be due to the glass vial manufacturing processes or to the crimping of the metallic sleeve that holds the rubber septum in place. Dimensional variations can result in a cartridge that will not fit the cartridge retainer or that will be loosely supported and movable therein. Eccentricities can result in a vial barrel that is not properly positioned or aligned within the body of the cartridge retainer. Eccentricities also can prevent the neck of the vial from sliding into the precisely dimensioned neck of the cartridge retainer. As a result, considerable quality control efforts must be undertaken to ensure that only cartridges that are within narrowly defined dimensional tolerances are used, and high reject rates occur. To reduce rejects and ensure that a larger number of vials can be accepted, prior art pens have included vial retainers with wider bodies that are intended to accommodate a greater range of eccentricities between the neck and the body of the vial. This results in larger pens even though it would be desirable to reduce the size.

Users of medication delivery pens are urged to disinfect both the puncture site and the distal end of the pen prior to each injection of medication. The disinfectant can react with the plastic of the prior art cartridge retainer to cause crazing or cracking.

Medication delivery pens also have been found to exhibit weeping or drooling near the interface of the needle assembly and the cartridge retainer. This weeping or drooling presents inconveniences to the user and creates the potential for an accumulation of medication at an external position on the pen and near the puncture site of the patient.

It is now believed that weeping or drooling is attributable to contact between the septum and the cork of the needle assembly during the injection of medication. In particular, the movement of the plunger distally in the vial urges the liquid in a distal direction. These distally directed forces urge liquid through the lumen of the needle cannula. How-

ever, these forces also cause a stretching of the septum in a distal direction. As noted above, the neck of the prior art cartridge retainer provides the primary support for the cartridge, and hence closely engages the metal sleeve which holds the septum to the vial. The distal stretching of the septum in response to fluid pressure urges the septum into direct contact with the cork on the needle assembly of the prior art medication delivery pen. The combination of fluid pressure and contact with the cork will sufficiently change the shape of the pierced septum to permit the weeping or drooling of medication between the septum and the needle cannula.

Still another problem with prior art medication delivery pens relates to the above described disposition of threads around the distal end of the prior art cartridge retainer. In particular, the threads begin at the distal tip of the prior art cartridge retainer and extend a short distance in a proximal direction. Even minor variations in dimensional tolerances can require the user to threadedly engage the cap of the needle assembly to the threads of the cartridge retainer before the proximal tip of the needle cannula has pierced the septum. In these instances, the beveled proximal tip of the needle cannula will pierce the septum while undergoing a rotational movement. This may cause the beveled tip to rip the septum and may further contribute to the above described drooling or weeping. Sufficiently large rips may not adequately reseal and can lead to a premature degradation of the medication stored in the vial.

SUMMARY OF THE INVENTION

The subject invention is directed to a two-piece cartridge retainer assembly that is particularly suitable for medication delivery pens. The cartridge retainer assembly includes a generally tubular body for surrounding the barrel of a vial and for supportingly engaging the converging wall that defines the shoulder of the vial. The cartridge retainer assembly further includes a needle mounting collar floatingly mounted to the body for surrounding the neck of the vial. The needle mounting collar may be diametrically dimensioned to closely engage the metallic sleeve which is crimped to the vial for holding the rubber septum in place. However, such close engagement is not essential. The needle mounting collar of the cartridge retainer assembly may also define an axial length for preventing contact between the rubber septum and the cap or cork of the needle assembly. Thus, drooling or weeping in response to contact between a distended septum and the cork of the needle assembly is substantially eliminated.

Floating between the needle mounting collar and the body of the cartridge retainer assembly enables the cartridge retainer assembly to accommodate a much greater range of eccentricities. Hence, the diametrical dimensions of the body of the cartridge retainer assembly can be reduced. Additionally, the two-piece design for the cartridge retainer assembly enables dissimilar materials to be used for the body and the needle mounting collar. For example, the body may be formed from any convenient transparent plastic material that will provide the necessary structural support and that will enable observation of the stopper positioned within the vial. The needle mounting collar, on the other hand, may be formed either from a thin metal or a plastic that exhibits appropriate resistance to disinfectants that may be used before or after each injection.

The secure but floatable connection of the needle mounting collar to the body may be achieved by a plurality of axial extending slots formed either on the body or the needle mounting collar of the cartridge retainer. The slots may define resiliently deflectable fingers. Each finger may be provided with tabs disposed and dimensioned to be snap fit into corresponding grooves in the opposing member. The tabs and grooves will prevent unintended axial separation of the needle mounting collar and the body of the cartridge retainer assembly. However, the resiliently deflectable fingers will permit a certain range of radial movement to accommodate dimensional variations and eccentricities in the cartridge being retained. Preferably the external threads on the needle mounting collar of the cartridge retainer assembly are spaced proximally from the extreme distal end. This proximal position ensures that the proximal tip of the needle cannula can pierce the septum in response to axial movement of the needle assembly and without relative twisting that could cause ripping of the septum. The twisting for threaded engagement of the needle assembly and the needle mounting collar will be carried out only after the beveled tip is fully within the vial and beyond the position where rotation of the needle can urge the sharp beveled edges into ripping or tearing engagement with the rubber septum.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of a medication delivery pen having a cartridge retainer assembly in accordance with the subject invention.

FIG. 2 is a perspective view of the assembled medication delivery pen incorporating the cartridge retainer assembly of the subject invention.

FIG. 3 is an end elevational view of the body of the cartridge retainer assembly.

FIG. 4 is a cross-sectional view taken along line 4—4 in FIG. 3

FIG. 5 is an end elevational view of the needle mounting collar of the cartridge retainer assembly.

FIG. 6 is a cross-sectional view taken along line 6—6 in FIG. 5.

FIG. 7 is a cross-sectional view taken along line 7—7 in FIG. 2.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

A cartridge retainer assembly in accordance with the subject invention is identified generally by the numeral 10 in FIGS. 1–7. Cartridge retainer assembly 10 is intended to be a part of a medication delivery pen 11 and includes elongate generally tubular body 12 with opposed proximal and distal ends 14 and 16 respectively and a cartridge receiving cavity 18 extending therebetween. A generally tubular needle mounting collar 20 is floatably mounted to distal end 16 of body 12. Body 12 and collar 20 of cartridge retainer assembly 10 both are described in greater detail below.

Cartridge retainer assembly 10 is dimensioned and configured to receive a cartridge assembly 22 therein. Cartridge assembly 22 includes a vial 23 with a generally tubular barrel 24 of diameter "a" with an open proximal end 26 and a distal end defined by an inwardly converging shoulder 28. A small diameter neck 30 projects distally from shoulder 28 of barrel 24 on vial 23, and is provided with a large diameter annular bead (not shown) extending circumferentially thereabout at the extreme distal end of neck 30. A pierceable and resealable rubber septum 32 extends completely across the open distal end defined by neck 30. Rubber septum 32 is

held in place by a metallic sleeve 34 which is crimped around the circumferential bead at the distal end of neck 30. Crimped metallic sleeve 34 defines an approximate diameter "b" which is less than diameter "a" of body 24. Medication such as insulin or heparin is pre-filled into vial 23 and is retained therein by a rubber stopper 36. Stopper 36 is in sliding fluid-tight engagement with the tubular wall of barrel 24. Distally directed forces on stopper 36 urge the medication from pen 11 as explained further below.

Medication delivery pen 11 further includes a prior art dosing apparatus identified generally by the numeral 38. Dosing apparatus 38 also is generally cylindrical and includes opposed proximal and distal ends 40 and 42 respectively. Threads are disposed at distal end 42 of prior art dosing apparatus 38 for releasable threaded engagement with proximal end 14 of body 12 of cartridge retainer assembly 10, as shown in FIG. 2. A plunger rod 44 projects distally from dosing apparatus 38 and is dimensioned to engage stopper 36 of cartridge assembly 22. The prior art dosing apparatus 38 includes known mechanisms therein for setting a selected dose of medication to be delivered by pen 11. A dispensing mechanism (not shown) is operative to drive plunger rod 44 a selected distance in a distal direction for moving stopper 36 a distance that will inject the selected dose of medication from cartridge assembly 22. Although a particular prior art dosing apparatus 38 is depicted in FIGS. 1 and 2, it is to be understood that other dosing apparatus can be used with the cartridge retainer assembly of the subject invention.

Medication delivery pen 11 further includes a prior art needle assembly 46 having a metallic needle cannula 48 with opposed proximal and distal tips 50 and 52 respectively and a lumen (not shown) extending entirely therethrough. A cork 54 is securely affixed at an intermediate position along needle cannula 48, and a cap 56 is securely affixed to cork 54. Cap 56 of prior art needle assembly 46 includes an array of internal threads (not shown) for removable mounting to cartridge retainer assembly 10.

As explained above, prior art cartridge assemblies 22 are subject to significant dimensional variation and eccentricities. In particular, the crimped mounting of metal sleeve 34 to neck 30 can result in diametrical or axially length differences from one cartridge to the next. Additionally, considerable eccentricities between neck 30 and body 24 are likely to exist.

Cartridge retainer assembly 10 accommodates the dimensional variations and eccentricities that exist in prior art cartridge assemblies 22. More particularly, as shown in FIGS. 3 and 4 body 12 of cartridge retainer assembly 10 includes a plurality of inwardly projecting supports 60 defining sections of ares concentric with body 12. Supports 60 define an inside diameter "c" which is greater than diameter "b" defined by crimped sleeve 34 of cartridge assembly 22. Supports 60 are separated from one another by anti-rotation notches 62. An inwardly projecting annular rim 64 is defined at the extreme distal end 16 of body 12 and in spaced relation to the supports 60. Thus, an annular locking groove 65 with an axially measure thickness "d" and an inside diameter "e" is disposed intermediate supports 60 and rim 64.

Portions of body 12 disposed proximally of supports 60 define a vial receiving chamber 66 of substantially uniform diameter "f" which is slightly greater than diameter "a" of vial barrel 24. Portions of body 12 proximally of chamber 66 are of slightly larger diameter and define a recess 68 for receiving a portion of dosing apparatus 38. An array of internal threads 70 in recess 68 engage threads on proximal end 42 of dosing apparatus 38. It is to be understood, however, that other releasable engagement means between dosing apparatus 38 and cartridge retainer assembly 10 can be provided. For example, internal threads can be formed on dosing apparatus 38 and corresponding external threads can be defined on cartridge retainer assembly 10.

Needle mounting collar 20 of vial retainer assembly 10 includes opposed proximal and distal ends 72 and 74 respectively as shown in FIGS. 5 and 6. Proximal end 72 is characterized by a plurality of anti-rotation projections 76 dimensioned and disposed for sliding engagement in notches 62 between arcuate supports 60 near distal end 16 of cartridge retainer body 12.

Needle mounting collar 20 further includes a plurality of spaced apart axially aligned slots 78 extending from proximal end 72 toward distal end 74. Slots 78 define a plurality of proximally extending resiliently deflectable fingers 80 on proximal end 72 of collar 20.

Proximal portions of deflectable fingers 80 are characterized by outwardly projecting locking ridges 82. Each locking ridge 82 has an axially measured thickness "h" which is slightly less than the thickness "d" defined by locking groove 65 at distal end 16 of body 12. Opposed locking ridges 82 further define an outside diameter "g" approximately equal to or slightly less than the diameter "e" defined by locking groove 65 in body 12.

Distal end 74 of needle mounting collar 20 includes a generally annular end wall 84 having an aperture 86 extending therethrough for access by proximal point 50 of needle cannula 48. An array of outwardly disposed threads 88 is defined intermediate proximal and distal ends 72 and 74 respectively. Threads 88 are disposed and dimensioned for engaging threads on prior art needle assembly 46.

Needle mounting collar 20 and cartridge retainer body 12 are lockingly engaged with one another prior to sale of pen 11 by merely urging proximal end 72 of collar 20 into distal end 16 of body 12. This assembly is carried out by first aligning anti-rotation projections 76 at proximal end 72 of collar 20 with anti-rotation notches 62 between supports 60 at distal end 16 of body 12. After sufficient movement of collar 20 and body 12 toward one another, the chamfer on locking ridges 82 will engage annular rim 64 of body 12 to generate radially inward deflection of fingers 80. After sufficient movement of collar 20 and body 12 toward one another, locking ridges 82 will pass proximally beyond rim 64. Fingers 80 will then resiliently return toward an undeflected condition to lockingly engage ridges 82 in annular locking groove 65.

Assembly of medication delivery pen 11 continues by inserting cartridge 22 into cartridge retainer assembly 10. More particularly, neck 30 and crimped metallic sleeve 34 of vial 22 are inserted in a proximal to distal direction into open proximal end 14 of body 12 of the cartridge retainer assembly. Crimped metallic sleeve 34 eventually will pass entirely through body 12, and further advancement of cartridge 22 into cartridge retainer assembly 10 will require entry of crimped metallic sleeve 34 into needle mounting collar 20. As noted above, considerable dimensional variation and eccentricities between the neck and body of prior art vials are known to exist. If such eccentricities do exist, crimped metallic sleeve 34 will cause collar 20 to float radially relative to body 12 into a position that conforms with any dimensional inconsistencies or eccentricities in cartridge 22. More particularly, forces generated by the distal advancement of cartridge 22 will cause resiliently deflectable fingers

80 of needle mounting collar 20 to deflect into a position that conforms with the actual location and alignment of crimped metallic sleeve 34. This floating movement will cause needle mounting collar 20 and body 12 of cartridge retainer assembly 10 to assume an eccentric alignment that conforms with an eccentrically aligned neck and body on a vial.

Further distally directed movement of vial 22 into cartridge retainer assembly 10 will cause shoulder 28 of cartridge 22 to seat against arcuate supports 60 of body 12. Supports 60 define the fully seated position of cartridge 22 in cartridge retainer assembly 10 and function to securely engage vial 22. In this fully seated position, as shown most clearly in FIG. 7, septum 32 of cartridge 22 is spaced proximally from distal wall 84 of needle mounting collar 20.

Dosing apparatus 38 may next be assembled to proximal end 14 of the body of cartridge retainer assembly 10 such that plunger rod 44 of dosing apparatus 38 engages stopper 36 of cartridge 22.

Medication delivery pen 11 may be used by mounting a needle assembly 46 to needle mounting collar 20 of cartridge retainer assembly 10. This mounting is achieved by moving needle assembly 46 in a proximal direction over needle mounting collar 20 until the threads (not shown) of cap 56 engage external threads 88 on needle mounting collar 20. As noted above, threads 88 of needle mounting collar 20 are spaced from the extreme distal end of needle mounting collar 20. Thus, the initial axial advancement of cap 56 over needle mounting collar 20 will cause proximal point 50 of needle cannula 48 to pierce rubber septum 32 of cartridge 22 prior to rotational threaded engagement of needle assembly 46 with needle mounting collar 20. Thus, the bevel which defines proximal point 50 will advance axially through septum 32 without a rotation that could tear rubber septum 32. After threads of cap 56 engage threads 88 of needle mounting collar 20, further advancement of needle assembly 46 requires relative rotation between cap 56 and needle mounting collar 20. It will be appreciated that needle mounting collar 20 is too small to be readily griped by the user of medication delivery pen 11, and is partly covered by cap 56. However, the relative rotation can be achieved by rotating body 12 of cartridge retainer assembly 10. In particular, as noted above, anti-rotation projections 76 of needle mounting collar 20 are engaged in anti-rotation slots 62 which are defined between adjacent supports 60 of body 12. Hence, rotation of body 12 is transmitted to needle mounting collar 20 and enables complete rotational engagement of needle assembly 46.

Use of medication delivery pen 11 proceeds in a conventional manner with dosing apparatus 38. As explained above, actuation of dosing apparatus 10 causes liquid medication in cartridge 22 to be urged in a distal direction. The medication will be urged through the lumen of needle cannula 48. This distally directed liquid pressure also will cause septum 32 to distend in a distal direction. However, as noted above and as shown in FIG. 7, septum 32 is spaced proximally from cork 54 of needle assembly 46, and will not be urged into contact with cork 54. Thus, the drooling or weeping of liquid medication can be substantially prevented. This is enabled because cartridge 22 is supported and accurately positioned by engagement of vial shoulder 28 with supports 60 of body 12. Hence neck 30 and crimped metallic sleeve 34 need not be closely engaged by needle mounting collar 20.

After medication delivery pen 11 has been used, needle assembly 46 is separated from needle mounting collar 20 and discarded. The user is encouraged to apply a disinfectant to the distal end of medication delivery pen 11. Disinfectants have the potential of adversely affecting some plastic materials that could be used in a medication delivery pen. However, the two-part construction of vial retainer assembly 10 enables needle mounting collar 20 to be made from a metal or other material that is resistant to disinfectants that may be applied by the user.

What is claimed is:

1. A cartridge retainer assembly for retaining a medication cartridge having a barrel and a neck, said cartridge retainer assembly comprising:

a generally tubular body having opposed proximal and distal ends and being dimensioned for securely receiving a barrel of a cartridge therein;

a generally tubular needle mounting collar having opposed proximal and distal ends and being dimensioned for receiving a neck of the cartridge therein; and

cooperating engagiment means on said needle mounting collar and said tubular body for preventing distal and proximal movement of said needle mounting collar with respect to said body and for providing transversely floatable engagement between said needle mounting collar and said body, whereby said engagement means enables said cartridge retainer assembly to accommodate dimensional variations and eccentricities of the cartridge when the neck of the cartridge is being inserted through said body and into said needle mounting collar.

2. The cartridge retainer assembly of claim 1, wherein said engagement means comprises a plurality of resiliently deflectable fingers on said needle mounting collar.

3. The cartridge retainer assembly of claim 2, wherein each of said resiliently deflectable fingers has a locking ridge thereon and wherein said engagement means further comprises a groove on said body engaging said locking ridges, said engagement of said locking ridges and said groove retain said needle mounting collar and said body in substantially fixed axial position relative to one another.

4. The cartridge retainer assembly of claim 1, wherein the engagement means of said needle mounting collar and said body further comprises means for preventing relative rotation between said needle mounting collar and said body.

5. The cartridge retainer assembly of claim 1, wherein said needle mounting collar and said body are formed from dissimilar materials.

6. The cartridge retainer assembly of claim 1, wherein said needle mounting collar comprises an array of external threads thereon for threadedly and releasably engaging a needle assembly, said threads on said needle mounting collar being disposed proximally of said distal end of said needle mounting collar.

7. A cartridge retainer assembly for retaining a medication cartridge having a barrel and a neck defining a smaller cross-section than the barrel, said cartridge retainer assembly comprising:

a generally tubular body having opposed proximal and distal ends and a chamber therebetween, said chamber being dimensioned and configured for engaging a barrel of a cartridge therein, said body further including at least one inwardly projecting support defining a distal end of said chamber and including at least one anti-rotation slot formed therein, and a annular rib spaced distally from said support and defining a locking groove therebetween;

a generally tubular needle mounting collar having opposed proximal and distal ends, said proximal end of said collar including at least one axially aligned anti-

rotation projection engaged in said at least one slot for preventing rotation between said needle mounting collar and said body, an outwardly projecting locking ridge engaged in said locking groove of said body for preventing distal and proximal movement of said needle mounting collar with respect to said body, and a plurality of resiliently deflectable fingers defined by a corresponding plurality of axially aligned slots extending from said proximal end to a location intermediate said ends, said grooves permitting deflection of said fingers to accommodate dimensional inconsistencies and eccentricities of a barrel and a neck of the cartridge.

8. The cartridge retainer assembly of claim 7, wherein said body is formed from a transparent plastic material and wherein said needle mounting collar is formed from a metallic material.

9. The cartridge retainer assembly of claim 7, wherein said plurality of slots on said needle mounting collar includes four slots extending into said proximal end and defining four resiliently deflectable fingers, said needle mounting collar further including said at least one anti-rotation projection comprising four anti-rotation projections disposed respectively at central positions on each said resiliently deflectable finger.

* * * * *

US005688251A

United States Patent [19]

Chanoch

[11] Patent Number: 5,688,251

[45] Date of Patent: Nov. 18, 1997

[54] CARTRIDGE LOADING AND PRIMING MECHANISM FOR A PEN INJECTOR

[75] Inventor: Lawrence H. Chanoch, Mahwah, N.J.

[73] Assignee: Becton Dickinson and Company, Franklin Lakes, N.J.

[21] Appl. No.: 530,527

[22] Filed: Sep. 19, 1995

[51] Int. Cl.[6] A61M 5/00

[52] U.S. Cl. 604/208; 604/186; 604/187; 604/232; 222/46; 222/309

[58] Field of Search 604/110, 186, 604/187, 188, 192, 195, 196, 221, 207-211, 232, 71, 72, 218, 224, 234; 222/46, 48, 309

[56] References Cited

U.S. PATENT DOCUMENTS

4,592,745	6/1986	Rex et al.	604/211
4,865,591	9/1989	Sams	604/186
4,936,833	6/1990	Sams	604/232
5,112,317	5/1992	Michel	604/208
5,226,895	7/1993	Harris	604/208
5,279,585	1/1994	Balkwill	604/207
5,304,152	4/1994	Sams	604/207
5,383,865	1/1995	Michel	604/232

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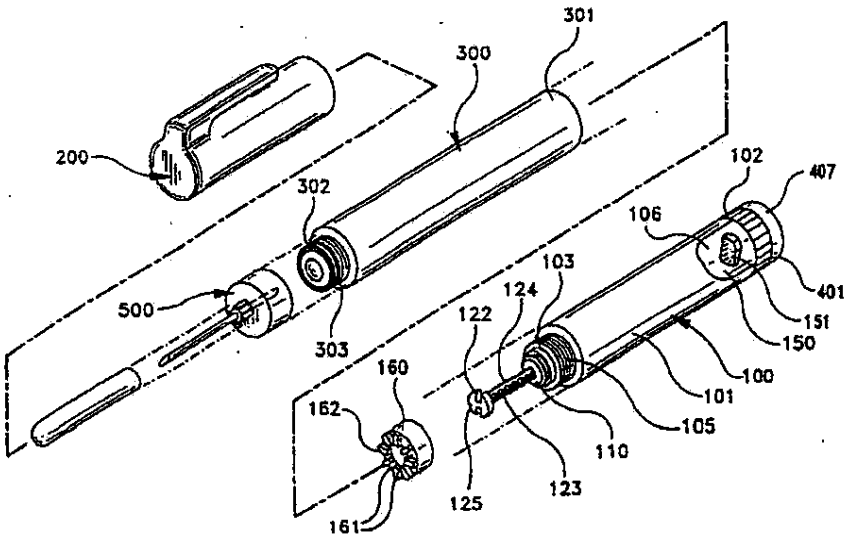
[57] ABSTRACT

A medication delivery pen is provided having a medication cartridge holder assembly, a pen body assembly and a cap. The reusable pen body assembly includes an improved loading and priming mechanism that allows the user to easily load a new cartridge and prime the pen without having to manually manipulate the pen's lead screw and related driving components.

9 Claims, 5 Drawing Sheets



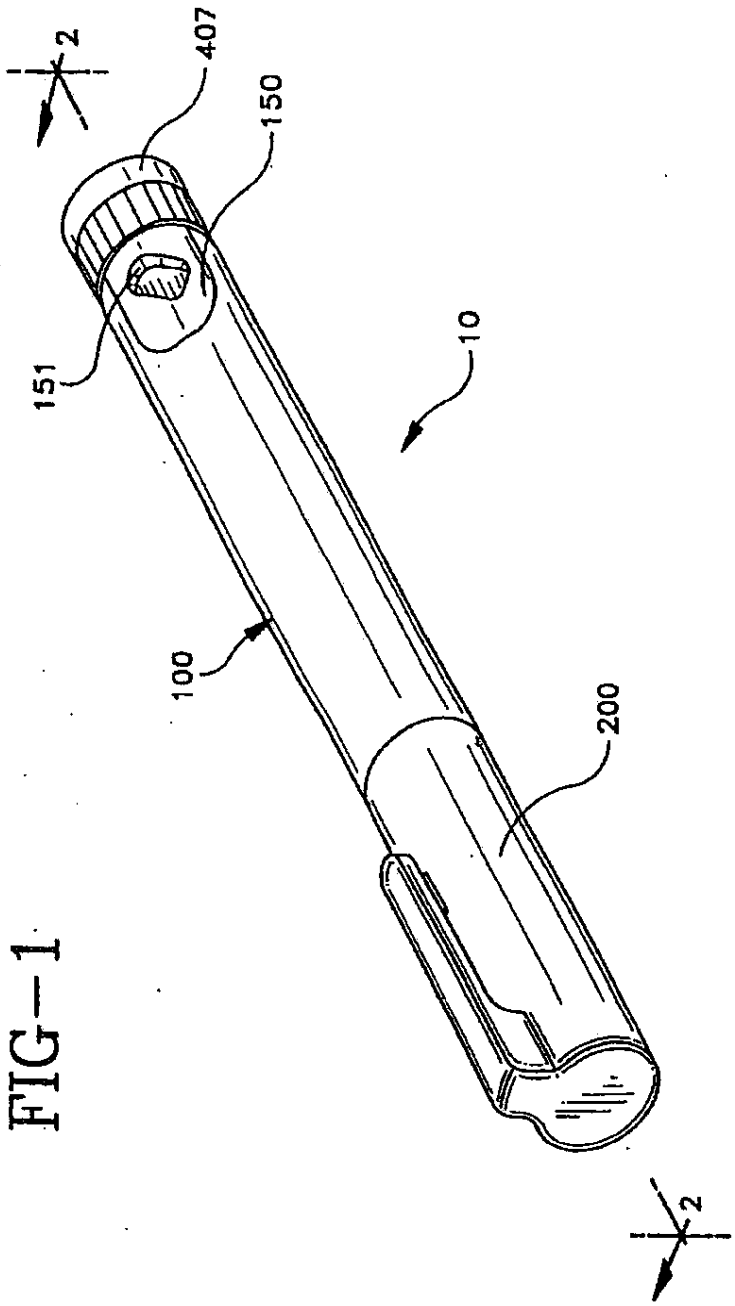
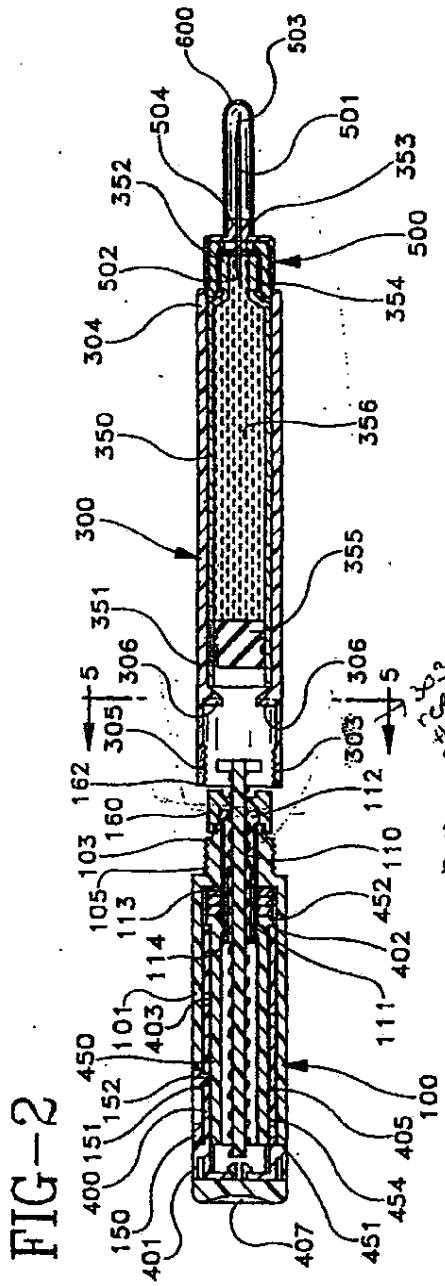


FIG-1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303
162
112
160
110
103
105
452
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403
450
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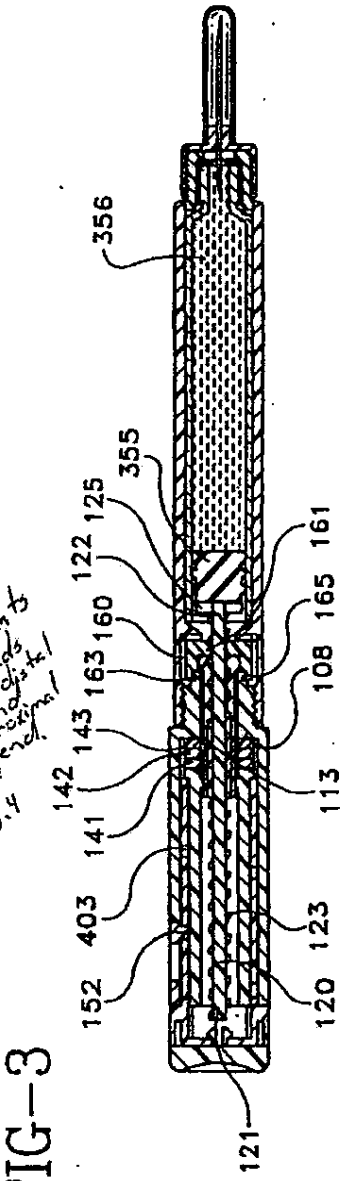
152
405
151
400
454
150
451
401
407

FIG-2


356
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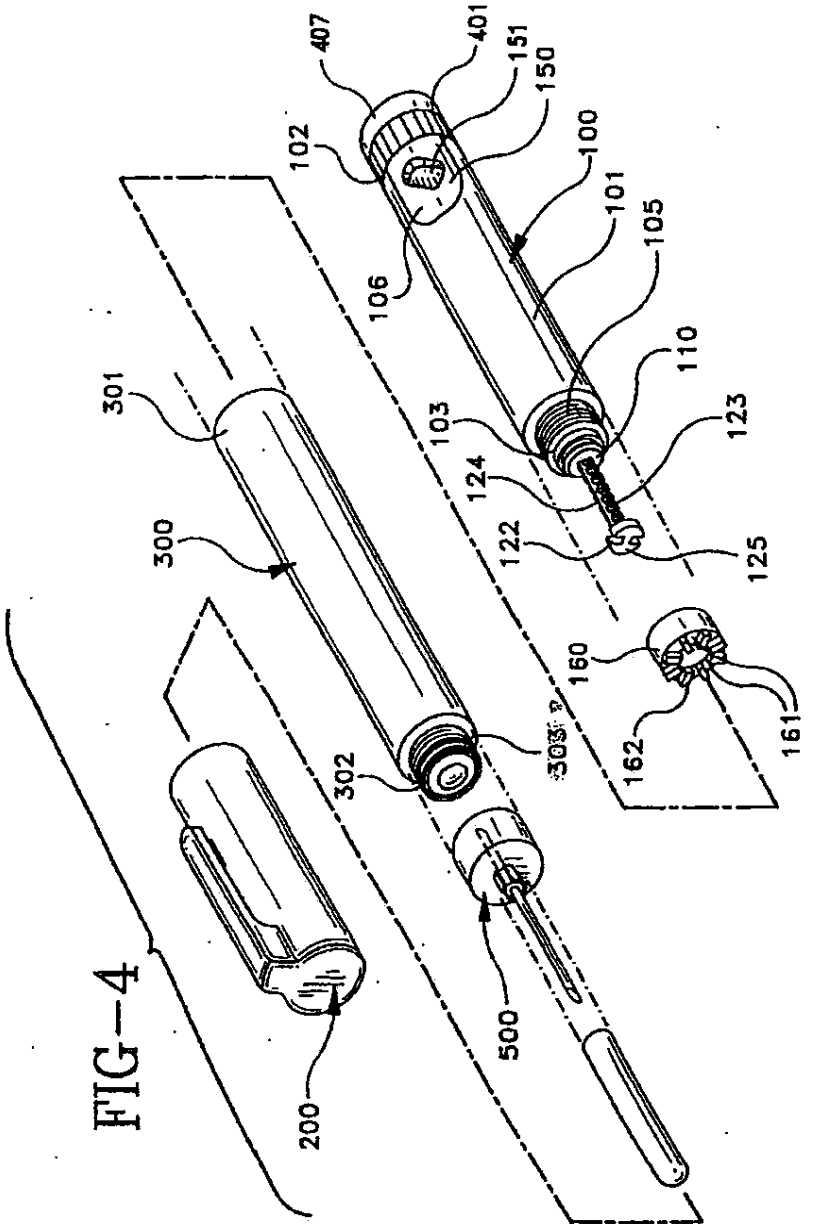
161
122
165
160
108
163
143
113
142
141
403
123
152
120
121

FIG-3


407
401
151
150
102
100
101
105
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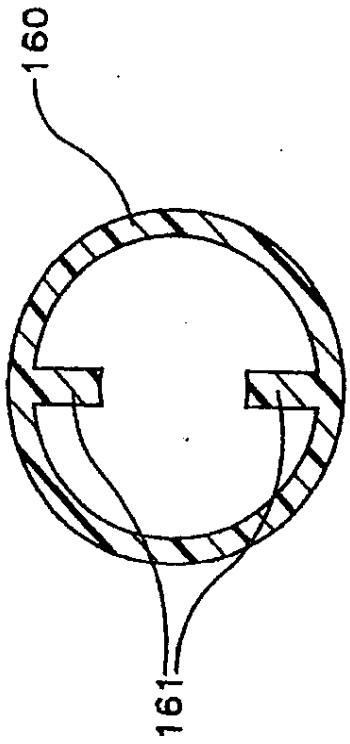
110
301
103
123
124
300
122
125
160
303
161
162
302
500
200

FIG-4



FIG—5

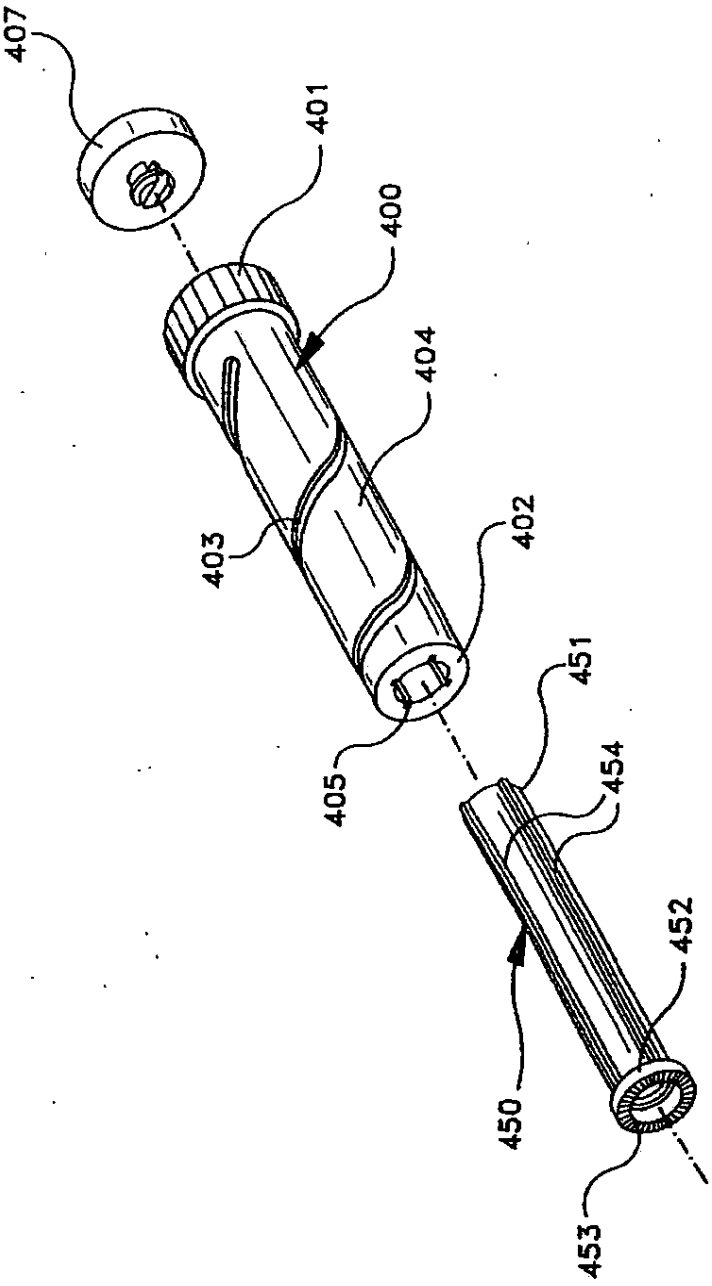


FIG-6

CARTRIDGE LOADING AND PRIMING MECHANISM FOR A PEN INJECTOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

The subject invention relates to an improved cartridge loading and priming mechanism for a medication delivery pen having a cartridge holder assembly and a pen body assembly removably mounted to the cartridge holder assembly for delivering selected doses of medication.

2. Description of Related Art

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula is mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal and accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula is withdrawn from the vial, and the medication is injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

The above described reusable medication delivery pen is effective and much more convenient for self-administration of medication than the typical hypodermic syringe and separate medication vial. However, the disassembly of the pen to remove empty medication vials and to insert new ones is an inconvenience. As a result, disposable pens have been developed. The prior art disposable medication delivery pen includes a vial of insulin or other such medication permanently encapsulated therein. The patient need merely connect a double-ended needle cannula to the disposable pen for each administration of medication. The prior art disposable pen can be discarded when the supply of medication permanently encapsulated therein has been exhausted.

Disposable medication delivery pens offer certain conveniences to the patient who is required to self-administer medication. However, the dose selecting and driving mechanisms of prior art medication delivery pens are fairy complex devices and costly to manufacture. Hence, a substantial cost penalty is associated with the convenience of using a disposable medication delivery pen.

Another problem with the above-described medication delivery pens is in loading and priming the penis. These pens usually utilize a lead screw and matching nut combination that translate a rotary dose setting motion into a linear lead screw motion required to expel medication from the pen or cartridge. In such a mechanism, the nut is allowed to rotate during medication delivery while rotation of the lead screw is prevented by means of a rigidly mounted ring with tabs extending into the lead screw. Therefore, as the nut turns the pre-selected amount, threads on the nut and lead screw cause the lead screw to move axially to deliver the medication. Then, when the cartridge is empty and must be replaced, the fully extended lead screw must be manually rotated and returned to a starting position to receive a new cartridge. However, manual rotation of the lead screw is very difficult since the tabbed ring is intended to prevent rotation of the lead screw.

SUMMARY OF THE INVENTION

It is an objective of the present invention to overcome the problem with moving the lead screw back into the pen during cartridge loading found in prior art pens by providing

a medication delivery pen having an improved cartridge loading and priming mechanism that allows a patient to easily load and prime the pen. The present invention provides a pen with a lead screw that is easily slid back into the pen during cartridge loading and thereby eliminates the need for a patient to manipulate an anti-rotation tabbed ring. In the present invention the lead screw does not stop sliding until the cartridge holder assembly has been fully threaded onto the pen housing and, therefore, provides automatic priming of the pen during the threading operation and causes the lead screw to automatically engage with a drive mechanism.

In particular, the medication delivery pen of the present invention includes a medication cartridge holder assembly that is selectively engageable with and disengageable from a pen body assembly. In particular, the medication delivery pen includes means for allowing the lead screw in the medication delivery pen to automatically and easily slide into and prime the medication delivery pen as the cartridge assembly approaches the pen body assembly, when the lead screw is in contact with the plunger in the cartridge. The medication pen also includes means for engaging the lead screw to the cartridge holder assembly as the cartridge is being threaded to the pen body assembly and means for engaging the lead screw to the drive mechanism when the cartridge holder assembly has been fully threaded to the pen body assembly.

These and other aspects, features and advantages of the present invention will become apparent from the following detailed description taken in conjunction with the accompanying drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the medication delivery pen of the subject invention;

FIG. 2 is a longitudinal cross-sectional view of an unassembled medication delivery pen shown in FIG. 1 along lines 2—2;

FIG. 3 is a longitudinal cross-sectional view of an assembled medication delivery pen shown in FIG. 2;

FIG. 4 is a exploded perspective view of the medication delivery pen shown in FIG. 1;

FIG. 5 is a cross-sectional view of the medication delivery pen shown in FIG. 2 along lines 5—5; and FIG. 6 is a further exploded perspective view of dose knob 400 and driver 450, shown in FIG. 2.

DETAILED DESCRIPTION

A medication delivery pen in accordance with the subject invention is identified generally by the numeral 10 in FIGS. 1–4. Medication delivery pen 10, as shown in FIGS. 1–4, includes a reusable pen body assembly 100, a cap 200, a cartridge holder assembly 300, and a needle cannula assembly 500. Cartridge holder assembly 300 includes opposed proximal and distal ends 301 and 302, respectively. Proximal end 301 of cartridge holder assembly 300 is dimensioned and configured to threadedly engage pen body assembly 100, as explained further herein. Distal end 302 of cartridge holder assembly 300 is configured to securely but releasably engage needle cannula assembly 500.

The preferred embodiment of reusable pen body assembly 100 is illustrated in detail in FIGS. 2–4. It is understood, however, that variations from this preferred embodiment may be provided, and are considered to be within the scope of the subject invention. Reusable pen body assembly 100 includes a cylindrical housing 101 having opposed proximal and distal ends 102 and 103. An array of external threads 105 extends proximally from distal end 103 for threaded engagement with threads 303 in proximal end 301 of cartridge holder assembly 300. Portions of housing 101 adjacent distal end 103 are characterized by an array of clutch teeth (not shown) molded therein. Proximal end 102 of housing 101 is characterized by a cut-out 106 formed therein for receiving a window insert 150 having a window 151 and a button 152.

Pen body assembly 100 further includes a nut 110 having opposed proximal and distal ends 111 and 112, respectively. Exterior surface regions of nut 110 between proximal and distal ends 111 and 112 define a plurality of longitudinally extending splines 113. Proximal end 111 of nut 110 is characterized by a plurality of longitudinally extending resilient fingers 114 with enlarged ends that enable snap engagement of nut 110 into other portions of pen body assembly 100 as explained further herein. Distal end 112 of nut 110 is radially enlarged to limit axial movement of nut 110 into distal end 103 of housing 101. Thus, nut 110 is axially constrained within housing 101. However, the dimensions and configurations of nut 110 and housing 101 permit free relative rotation therebetween.

Pen body assembly 100 further includes a clutch assembly having a proximal clutch 141, a distal clutch 143 and an annular spring 142 biasingly engaged therebetween. Proximal and distal clutches 141 and 143 are both configured for non-rotatable engagement over splines 113 of nut 110. Distal clutch 143 includes an array of distally facing saw teeth (not shown) dimensioned, disposed and configured for engagement with the teeth (not shown) on interior surface 108 of housing 101, such that distal clutch 143 can rotate only in one direction relative to housing 101. Proximal clutch 141 includes an array of proximally facing teeth (not shown) which are also configured for unidirectional rotation as explained further herein.

Pen body assembly 100 further includes a drive mechanism having a generally cylindrical driver 50 with opposed proximal and distal ends 451 and 452. Driver 450 is slidably inserted into housing 101 of pen body assembly 100 such that distal end 452 of driver 450 is snap fit over the enlarged ends of resilient fingers 114 at proximal end 111 of nut 110. This snap fit engagement prevents axial movement between nut 110 and driver 450, but permits free relative rotational movement within housing 101. Distal end 452 of driver 450 is also characterized by an array of saw teeth (not shown) that engage with the saw teeth on proximal clutch 141. Outer surface regions of driver 450 are characterized by splines 454 extending radially outwardly thereon and along a substantial portion of the length of driver 450.

Pen body assembly 100 further includes a dose knob 400 which is a hollow generally cylindrical structure having opposed proximal and distal ends 401 and 402 and opposed inner and outer surfaces. As shown in FIG. 6, the inner surface is characterized by longitudinally extending grooves 405 which are disposed and dimensioned for engagement with splines 454 on driver 450. More particularly, dose knob 400 is spline mounted over driver 450 within housing 101 of pen body assembly 100. Thus, axially extending grooves 405 in dose knob 400 engage splines 454 of driver 450 to prevent relative rotation therebetween, but permitting relative axial movement. The outer surface of dose knob 400 is characterized by a helical groove 403 with dosage indicia to define dose amounts corresponding to different positions along helical groove 403. Proximal end 401 of dose knob 400 is characterized by a gnarled exterior surface to facilitate manipulation for setting a selected dose having an

actuator button 407 snapped therein to permit relative rotation therebetween.

Insert 150 is snapped into engagement with cut-out 106 in the proximal end 102 of housing 101. Insert 150 includes a window 151 therethrough and button 152 on an interior face that is dimensioned and disposed to engage with helical groove 403 on dose setting knob 400. Button 152 and window 151 are disposed to also enable the dosage indicia on dose setting knob 400 to be visible through window 151 as dose knob 400 is rotated.

Pen body assembly 100 includes a lead screw 120 with opposed proximal and distal ends 121 and 122 and an array of external threads 123. External threads 123 are characterized, however, by a pair of opposed axially extending grooves 124 which extend from an enlarged head 125 at distal end 122 substantially to the proximal end 121. Threads 123 are threadably engaged in nut 110, such that proximal end 121 of lead screw 120 is within housing 101 and distal end 122 projects distally beyond housing 101. Threads 123 on lead screw 120 have exactly the same pitch and the same hand as threads 105 on distal end 103 of housing 101.

Pen body assembly 100 further includes an anti-rotation ring 160, shown in FIGS. 2-5, having a pair of tabs 161 extending therein and splines 162 on its distal surface. Each tab 161 slidable engages groove 124 on lead screw 120 to allow anti-rotation ring 160 to travel on and rotate with lead screw 120. Thus, lead screw 120 can slidably move relative to anti-rotation tabs 161, but is prevented from rotating relative to anti-rotation tabs 161.

Pen body assembly 100 is assembled by placing nut 110 into housing 101 from distal end 103. Clutch assembly 141,142 and 143 then is mounted over splines 113 on nut 110. Driver 450 is then inserted into proximal end 102 of housing 101, and is urged sufficiently in a distal direction for snap fit engagement with nut 110. In this snapped engagement, the saw teeth of distal clutch 143 will be secured in engagement with the teeth in of housing 101, and the saw teeth of proximal clutch 141 will be engaged with the saw teeth at distal end 452 of driver 450. Spring 142 will maintain constant selected pressure between these intercaged saw teeth. Insert 156 then is positioned over dose knob 400 such that button 152 of insert 150 is engaged in the helical groove 403 in dose knob 400. The temporarily assembled insert 150 and dose knob 400 then are into housing 101. Lead screw 120 then is threaded into nut 110, and actuator button 407 is snapped into engagement with proximal end 401 of dose knob 400. Finally, anti-rotation ring 160 is slid onto lead screw 120 and a retaining ring 163 on ring 160 is rotatably attached to a receiving ring 165 at distal end 103 of pen housing 101.

Cartridge holder assembly 300, shown in detail in FIGS. 2 and 3, includes a molded housing 304 which extends from proximal end 301 to distal end 302 of cartridge holder assembly 300. Housing 304 includes a mounting cavity 305 extending inwardly from proximal end 301. Mounting cavity 305 is characterized by an array of internal threads 303 for threaded engagement with external threads 105 on distal end 103 of housing 101. A set of splines 306 are located in proximal end 301 of cartridge holder assembly 300 to receive splines 162 on anti-rotation ring 160 when cartridge holder assembly 300 is threaded onto housing 101 to prevent cartridge holder assembly 300 from rotating with respect to lead screw 120 but continue to rotate with respect to pen housing 101. However, when pen 10 is fully assembled, splines 162 are fully engaged with splines 306 so that lead screw 120 is then engaged with the remaining drive mechanism in the pen and ready for dose setting and dispensing operations.

Cartridge holder assembly 300, further includes a medication cartridge 350 securely retained in housing 304 between proximal end 301 and distal end 302. Medication cartridge 350 includes an open proximal end 351 and a distal end 352 having a pierceable elastomeric seal 353 securely mounted thereto. A cap 354 extends between housing 304 and cartridge 350 for securely and permanently holding medication cartridge 350 in housing 304. A plunger 355 is disposed in sliding fluid tight engagement in cartridge 350. As shown in FIG. 3, plunger 355 is disposed in primed contact with plunger 355 of medication cartridge 350 when fully threaded to cartridge holder assembly 300. Portions of cartridge 350 between plunger 355 and seal 353 are filled with a medication 356, such as insulin.

Needle cannula assembly 500 includes a double ended needle cannula 501 having opposed proximal and distal points 502 and 503, respectively, and a lumen extending axially therebetween. A mounting hub 504 is engaged on needle cannula 501 and is threadably engageable with cap 354 of cartridge holder assembly 300. The relative location of mounting hub 504 ensures that proximal point 502 of needle cannula 501 will pierce seal 353 when mounting hub 504 is engaged with cap 354. Needle cannula assembly 500 further includes a shield 600 removably mounted thereon for protecting against accidental needle sticks until immediately prior to use of pen 10.

As noted above, pen body assembly 100 is reusable and cartridge holder assembly 300 is disposable. More particularly, cartridge 350 in cartridge holder assembly 300 will contain a volume of medication 356 sufficient for administration of several doses. After exhaustion of the medication 356, cartridge holder assembly 300 will be threadedly disengaged from pen body assembly 100 and discarded. A new cartridge holder assembly 300 may then be mounted to the reusable pen body assembly 100.

To effect the mounting of a new cartridge holder assembly 300 to the reusable pen body assembly 100, the patient need merely advance distal end 122 of lead screw 120 into cartridge holder assembly 300 until distal end 122 of lead screw 120 engages plunger 355. Assembly continues by merely exerting axial forces on actuator button 407 and on cartridge holder assembly 300 Additionally, friction between plunger 355 and cartridge 350 and fluid forces exerted by medication 356 and seal 353 will prevent axial advancement of lead screw 120 beyond the position depicted in FIG. 3 during assembly. Additionally, the splined engagement of distal clutch 143 with nut 110 and the engagement of the teeth on distal clutch 143 with the corresponding teeth in housing 101 prevent independent rotation of nut 110 with respect to housing 101, during this initial mounting of reusable pen body assembly 100 with a new cartridge holder assembly 300. Therefore, axial forces exerted on actuator button 407 will cause housing 101 to rotate and advance towards cartridge holder assembly 300 as nut 110 rotates on threads 123 of lead screw 120.

After sufficient axial advancement, threads 105 at distal end 103 of pen body housing 101 will engage internal threads 303 at proximal end 301 of cartridge holder assembly 300. As noted above, external threads 105 at distal end 103 of housing 101 have exactly the same pitch and hand as threads 123 on lead screw 120. Hence, further axial forces exerted on actuator button 407 will cause the simultaneous threaded advancement of housing 101 along lead screw 120 and into cavity 305 at proximal end 301 of cartridge holder assembly 300. Because of the identical pitches, lead screw 120 will move proximally relative to pen body housing 101, while pen body housing 101 and cartridge holder assembly

300 are approaching their fully seated and threaded condition. When fully seated and threaded, lead screw 120 is fully engaged to the drive mechanism and can be driven by the drive mechanism when medication dispensing is desired.

The assembled reusable pen body assembly 100 and cartridge holder assembly 300 may be stored until a selected dose of medication is required. Just prior to use, a needle cannula assembly 500 may be threadedly engaged to distal end 302 of cartridge holder assembly 300. This threaded engagement will cause proximal point 502 of needle cannula 501 to pierce seal 353 and provide communication with medication 356. Shield 600 may then be removed.

A desired dose of medication 356 is then set by rotating dose knob 400 until indicia corresponding to the desired dose appears in window 151 of insert 150. The engagement of button 152 on insert 150 in helical groove 403 in dose knob 400 will cause a threaded retraction of dose knob 400 relative to housing 101 of reusable pen body assembly 100. This threaded retraction of dose knob 400 will cause a simultaneous rotation of driver 450 splined thereto. However, nut 110 will not rotate because the saw teeth on distal clutch 143 and the saw teeth on interior portions of housing 101 are locked to prevent rotation in that direction. Proximal clutch 141 is splined to nut 110, and hence also will not turn. However, saw teeth 453, shown in FIG. 6, at distal end 452 of driver 450 are shaped to allow rotation relative to proximal clutch 141 and provide an audible click for each unit of medication in the selected dose. This is helpful for visually impaired patients who may be required to set doses and administer insulin or other medication to themselves. Annular spring 142 contributes to the engagement that provides these audible clicking sounds.

When the desired dose is set, injection is achieved by merely pushing on actuator button 407. This causes dose knob 400 to turn about helix 403 relative to pen body housing 101, and driver 450 rotates through the same number of degrees. This rotation is opposite to the rotation generated by the dose setting procedure, and the rotational freedom of the clutch assembly 140 is reversed. Thus, as driver 450 turns the previously clicking proximal clutch 141 is locked to and turns with driver 450. This driving movement of proximal clutch 141 causes a corresponding rotational movement of nut 110 because of the splined engagement therebetween. Distal clutch 143 is now free to rotate against the saw teeth on housing 101, and makes an audible clicking indication during injection of medication.

Rotation of lead screw 120 is prevented by splines 306 unitary molded in cartridge holder assembly 300 mating with splines 162 on anti-rotation ring 160 engaged with lead screw 120 and causes lead screw 120 to be engaged with the drive mechanism. Therefore, as nut 110 rotates under the driving action of proximal clutch 141 and driver 450, lead screw 120 will be advanced axially into cartridge holder assembly 300. This axial advancement of lead screw 120 causes distal end 122 to urge plunger 355 distally into cartridge 350, and hence causes medication 356 to be injected through needle cannula 501. Injection will be terminated when proximal end 401 of dose knob 400 engages proximal end 102 of pen body housing 101.

Upon completion of the injection, needle cannula assembly 500 may be disengaged from cartridge holder assembly 300 and safely discarded. Cap 200 may be mounted over cartridge holder assembly 300, and pen 10 may be stored or carried in a convenient location until the next dose of medication is required. A subsequent dose of medication will be set in exactly the manner as described above. However, for such a subsequent dose, lead screw 120 and plunger 355 will be in a partly advanced position as a starting point. Dose setting and injections can be carried out until all of medication 356 has been used. Cartridge holder assembly 300 may then be threadedly disengaged from pen body assembly 100, and slidably separated from lead screw 120. The separated cartridge holder assembly may then be discarded and replaced as described above.

While the invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. In particular, the reusable pen body assembly may have other driving and/or clutch mechanisms. Additionally, different means for preventing and/or enabling rotation during the dose setting and injection phases may be provided. Similarly, other means for mounting needle cannula to the cartridge holder assembly may be provided. These various optional constructions will be apparent to those skilled in the an after having read the subject disclosure.

What is claimed is:

1. A medication delivery pen comprising:

a cartridge holder assembly for holding a cartridge having a plunger, said cartridge holder assembly having a plurality of threads at a proximal end; and

a pen body assembly releasably mountable on said cartridge holder assembly of said medication delivery pen for moving said plunger within said cartridge, said pen body assembly comprising:

a plurality of threads at a distal end for threading with said plurality of threads in said cartridge holder assembly;

a lead screw extending from the distal end for engaging the plunger in the cartridge in said cartridge holder;

means in said pen body assembly for driving said lead screw into said cartridge to move the plunger in the distal direction;

means in said pen body assembly for disengaging said driving means from said lead screw to permit said lead screw to automatically and easily retract into said pen body assembly as said pen body assembly approaches and is being threaded to said cartridge holder assembly; and

means in said pen body assembly for engaging said driving means to said lead screw to prime said medication delivery pen, when said pen body assembly is fully threaded onto said cartridge holder assembly,

wherein said means for disengagin and means for engaging include:

an anti-rotation ring slidably mounted on said lead screw to prevent said lead screw from rotating with respect thereto, said anti-rotation ring having a spline extending in the distal direction into said cartridge holder assembly; and

a spline located within said cartridge holder assembly for mating with said spline on said anti-rotation ring to prevent said lead screw from rotating with respect to said cartridge holder assembly and engage said lead screw to said driving means, when said pen body assembly is fully threaded onto said cartridge holder assembly.

2. A medication delivery pen according to claim 1, wherein said lead screw includes a longitudinal groove and said anti-rotation ring includes a tab that is received in said groove to prevent said lead screw from rotating with respect to said anti-rotation ring.

3. The medication delivery pen of claim 1, wherein said cartridge holder assembly further comprises a housing unitarily molded from a plastic material with said spline being a unitary portion of said housing.

4. A medication delivery pen according to claim 1, wherein:

said plurality of threads in said pen body assembly are dimensioned and have a pitch for threaded engagement with said plurality of threads at the proximal end of said cartridge holder assembly; and

said lead screw further comprises a proximal end disposed in said pen body assembly with an array of threads extending between the proximal end and the distal end of said lead screw and having a pitch substantially equal to said pitch of said plurality of threads in said pen body assembly.

5. The medication delivery pen of claim 1, wherein said pen body assembly further comprises dose setting means in said pen body assembly for defining specified distances of travel for said lead screw corresponding to selected doses of medication to be delivered.

6. The medication delivery pen of claim 1, further comprising a needle cannula assembly that is selectively engageable and disengageable from the distal end of said cartridge holder assembly.

7. A medication delivery pen comprising:

a cartridge holder assembly for holding a cartridge having a plunger, said cartridge holder assembly having a plurality of threads at a proximal end; and

a pen body assembly releasably mountable on said cartridge holder assembly of said medication delivery pen for moving said plunger within said cartridge, said pen body assembly comprising:

a plurality of threads at a distal end for threading with said plurality of threads in said cartridge holder assembly;

a lead screw extending from the distal end for engaging the plunger in the cartridge in said cartridge holder;

means in said pen body assembly for driving said lead screw into said cartridge to move the plunger in the distal direction;

means in said pen body assembly for disengaging said driving means from said lead screw to permit said lead screw to automatically and easily retract into said pen body assembly as said pen body assembly approaches and is being threaded to said cartridge holder assembly; and

means in said pen body assembly for engaging said driving means to said lead screw to prime said medication delivery pen, when said pen body assembly is fully threaded onto said cartridge holder assembly,

wherein said means for disengaging and means for engaging include:

an anti-rotation ring slidably mounted on said lead screw to prevent said lead screw from rotating with respect thereto, said anti-rotation ring having a plurality of splines extending in the distal direction into said cartridge holder assembly; and

a plurality of splines located within said cartridge holder assembly for mating with said plurality of splines on said anti-rotation ring to prevent said lead screw from rotating with respect to said cartridge holder assembly and engage said lead screw to said driving means, when said pen body assembly is fully threaded onto said cartridge holder assembly.

8. A medication delivery pen comprising:

a medication-containing cartridge holder assembly including:

an open proximal end having an array of threads,

a cartridge having a pierceably sealed distal end, and

a plunger in sliding fluid tight engagement within said cartridge at a location distally of said array of threads; and

a pen body assembly releasably mountable on said medication-containing cartridge holder assembly of said medication delivery pen for moving said plunger within said cartridge, said pen body assembly having:

a housing surrounding said pen body assembly and having opposed proximal and distal ends, said distal end having an array of threads dimensioned and having a pitch for threaded engagement with said array of threads at said proximal end of said medication-containing cartridge holder assembly,

a lead screw having a proximal end disposed in said housing, a distal end projecting beyond said distal end of said housing for selective engagement with said plunger, and an array of threads extending between said proximal and distal ends of said lead screw and having a pitch substantially equal to said pitch of said array of threads at said distal end of said pen body assembly,

driver means in said pen body assembly for moving said lead screw distally into said pen body assembly by preselected amounts,

dose setting means in said pen body assembly for defining specified distances of distal travel for said lead screw corresponding to selected doses of medication to be delivered and causing said driver means to move said lead screw distally a preselected amount corresponding to a selected dose, and

means in said pen body assembly for engaging said lead screw and said driver means and preventing said lead screw from moving in a proximal direction into said pen body assembly, when said pen body assembly is fully threaded onto said medication-containing cartridge holder assembly.

9. A medication delivery pen according to claim 8, wherein said means for engaging said lead screw and said driver means and preventing said lead screw from moving in a proximal direction into said pen body assembly include:

an anti-rotation ring slidably mounted on said lead screw to prevent said lead screw from rotating with respect thereto, said anti-rotation ring having a spline extending in the distal direction into said medication-containing cartridge holder assembly; and

a spline located within said medication-containing cartridge holder assembly for mating with said spline on said anti-rotation ring to prevent said lead screw from rotating with respect to said medication-containing cartridge holder assembly and engage said lead screw to said driver means, when said pen body assembly is fully threaded onto said medication-containing cartridge holder assembly.

* * * * *

United States Patent [19]

Holm et al.

[11] Patent Number: 4,973,318

[45] Date of Patent: Nov. 27, 1990

[54] DISPOSABLE SYRINGE

[75] Inventors: Niels E. Holm, Birkerod; Allan Spork, Lyngby; Klaus Thogersen, Klampenborg; Anders Bressendorff, Virum; Jorn Rex, Roskilde, all of Denmark

[73] Assignee: D.C.P. AF 1988 A/S, Denmark

[21] Appl. No.: 308,399

[22] Filed: Feb. 9, 1989

[30] Foreign Application Priority Data

Feb. 10, 1988 [DK] Denmark 692/88

[51] Int. Cl.[5] A61M 5/00

[52] U.S. Cl. 604/208; 604/211; 604/218

[58] Field of Search 604/206, 207, 208, 209, 604/210, 211, 187, 232, 236, 246, 248, 192, 263, 71, 72, 186, 218

[56] References Cited

U.S. PATENT DOCUMENTS

1,997,129	4/1935	Taylor et al.	
2,605,763	8/1952	Smoot	
2,695,023	11/1954	Brown	
2,718,299	9/1955	Atwater et al.	
2,826,195	3/1958	Ashkenaz	
3,138,157	6/1964	Ziherl et al.	604/71
3,348,545	10/1967	Sarnoff et al.	
3,517,668	6/1970	Brickson	
3,790,048	2/1974	Luciano et al.	
3,894,663	7/1975	Carhart et al.	
3,905,366	9/1975	Callahan et al.	
3,977,574	8/1976	Thomas	
4,022,207	5/1977	Citrin	
4,099,548	7/1978	Sturm et al.	
4,103,684	8/1978	Ismach	604/71
4,244,366	1/1981	Raines	
4,246,898	1/1981	Travalent et al.	
4,275,729	6/1981	Silver et al.	
4,395,921	8/1983	Oppenlander	
4,413,760	11/1983	Paton	
4,415,101	11/1988	Shapiro et al.	
4,457,712	7/1984	Dragan	
4,470,317	9/1984	Sabloewski et al.	
4,475,905	10/1984	Himmelstrup	
4,498,904	2/1985	Turner et al.	
4,583,973	4/1986	Humphrey et al.	604/218
4,583,978	4/1986	Porat et al.	
4,592,745	6/1986	Rex et al.	

FOREIGN PATENT DOCUMENTS

0037696	4/1960	European Pat. Off.
0064858	5/1981	European Pat. Off.
0143895	8/1984	European Pat. Off.
0226718	12/1985	European Pat. Off.
730971	1/1943	Fed. Rep. of Germany
1149735	12/1957	France
1170312	1/1959	France
1445659	6/1966	France
CH84/00167	6/1985	PCT Int'l Appl.
CH86/00151	5/1987	PCT Int'l Appl.
WO88/07874	10/1988	PCT Int'l Appl.
293302	12/1953	Switzerland
991766	5/1965	United Kingdom
1145483	3/1969	United Kingdom
1225495	3/1971	United Kingdom
2109690	2/1982	United Kingdom

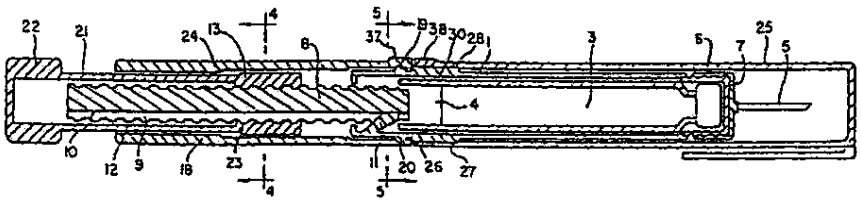
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Willian Brinks Olds Hofer Gilson & Lione

[57] ABSTRACT

A disposable syringe includes first and second housing elements which are coupled together for rotation without axial movement therebetween. The first housing element receives a cartridge of a solution to be injected, and mounts a liquid outlet needle at its front end. A piston rod is disposed in the second housing element to move axially therein, and this piston rod includes a rod element and a nut element. The rod element is coupled to the first housing element to move axially therein without relative rotation therewith, and the nut element is threaded to the rod element for telescoping movement therewith and is configured to move axially in the second housing element without relative rotation therein. A pressure receiving element is mounted on the nut element. The housing, rod, nut and pressure receiving elements cooperate such that relative rotation between the housing elements in a selected direction causes relative rotation between the nut and rod elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element. A protective cap is removably mounted over the first housing element and is configured to abut second housing element while mounted in place on the first housing element. This protective cap is engaged with the first housing element such that rotation of the cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

30 Claims, 9 Drawing Sheets



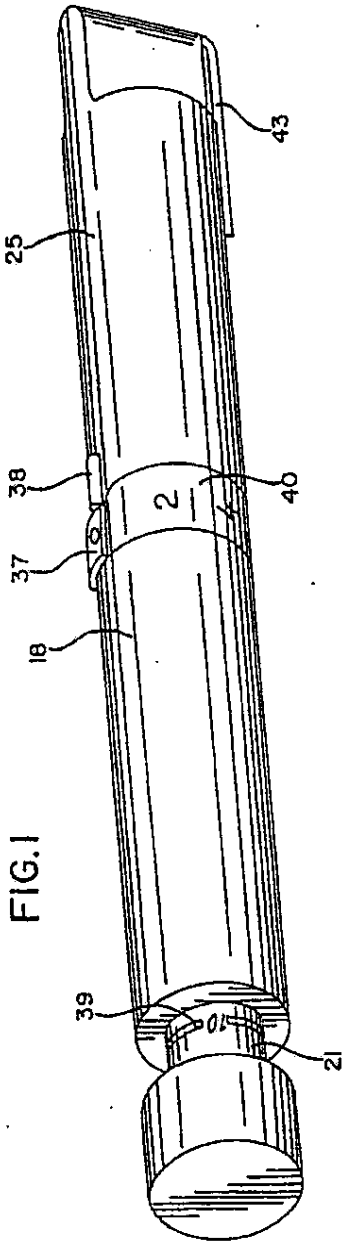


FIG. 1

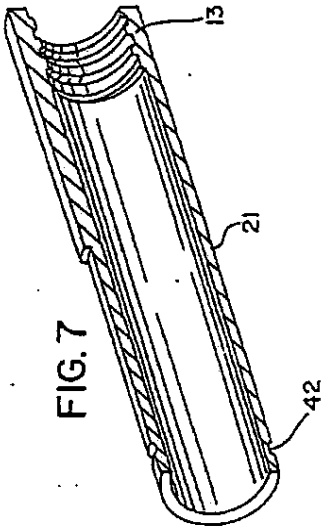


FIG. 7

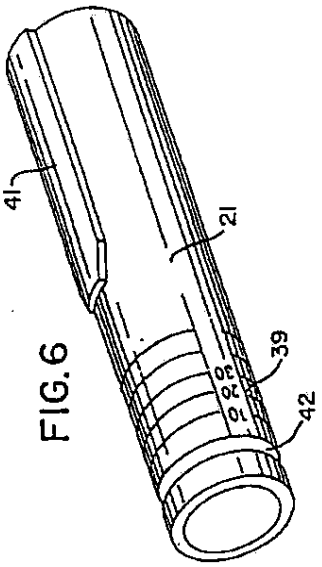


FIG. 6

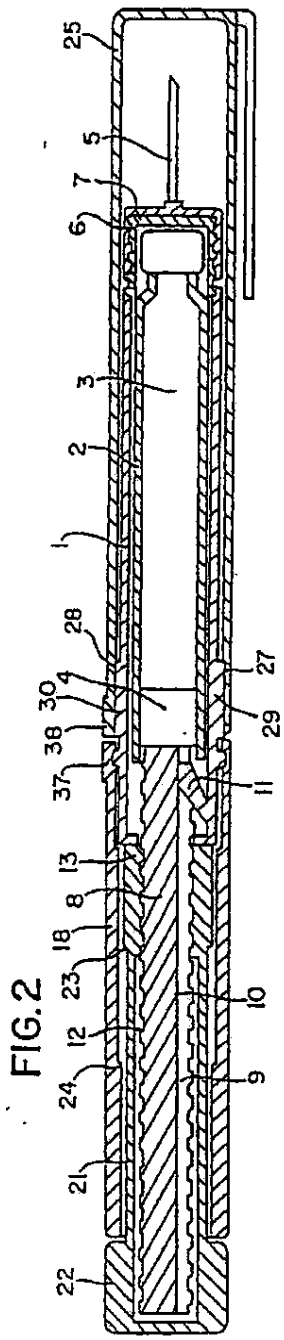


FIG.2

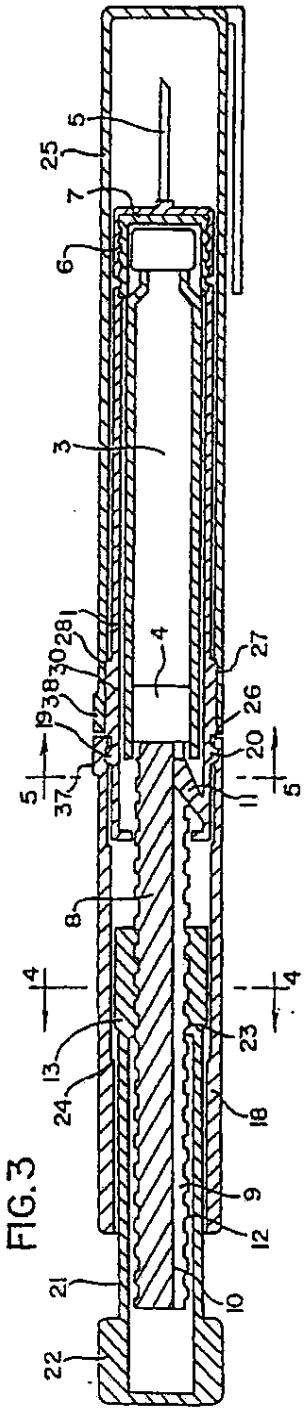


FIG.3

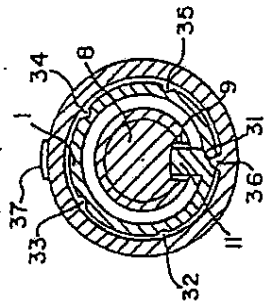


FIG.5

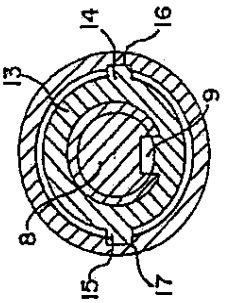


FIG.4

FIG. 8

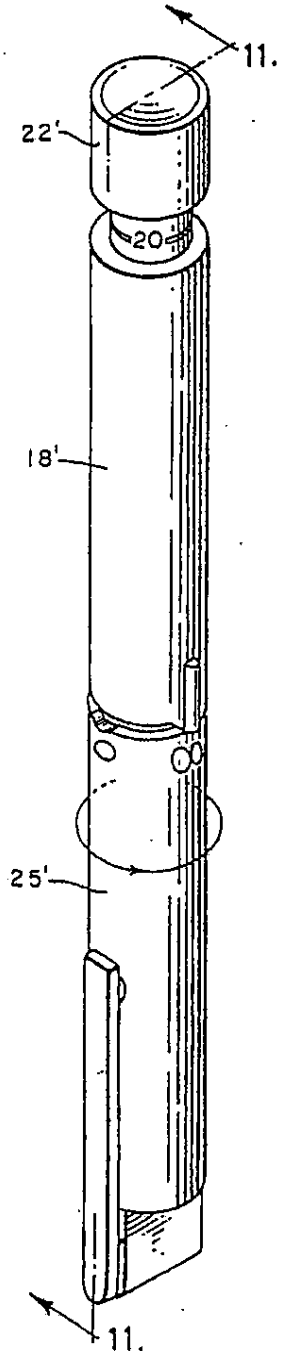


FIG. 9

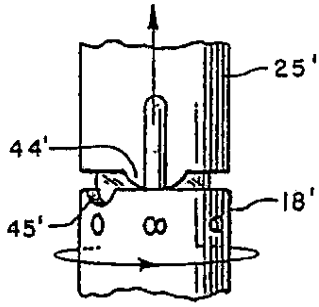
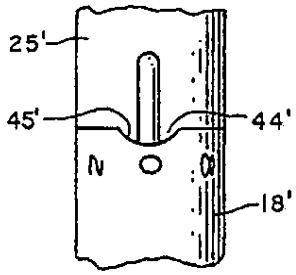


FIG. 10



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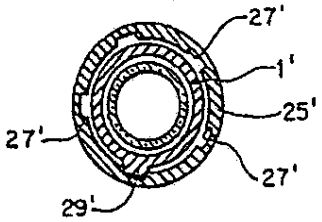

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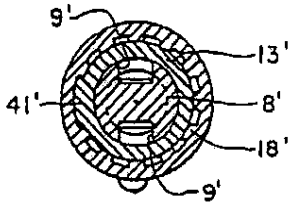

FIG. 11

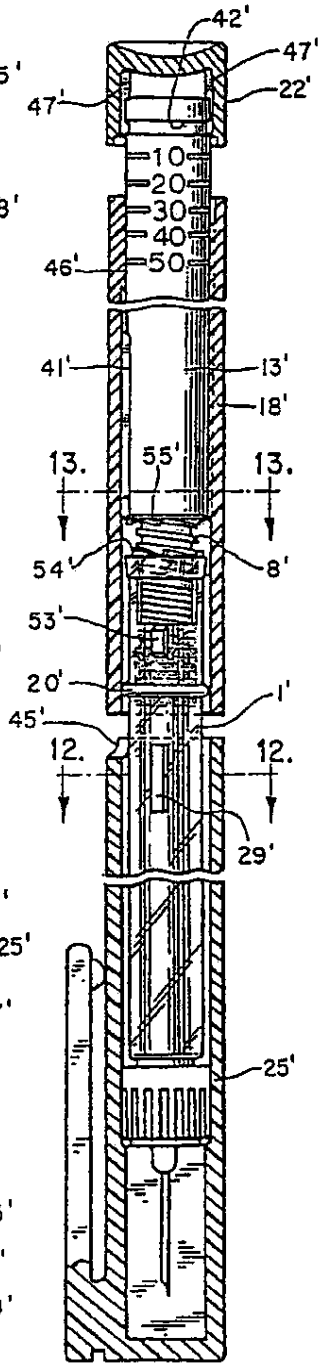

FIG. 14

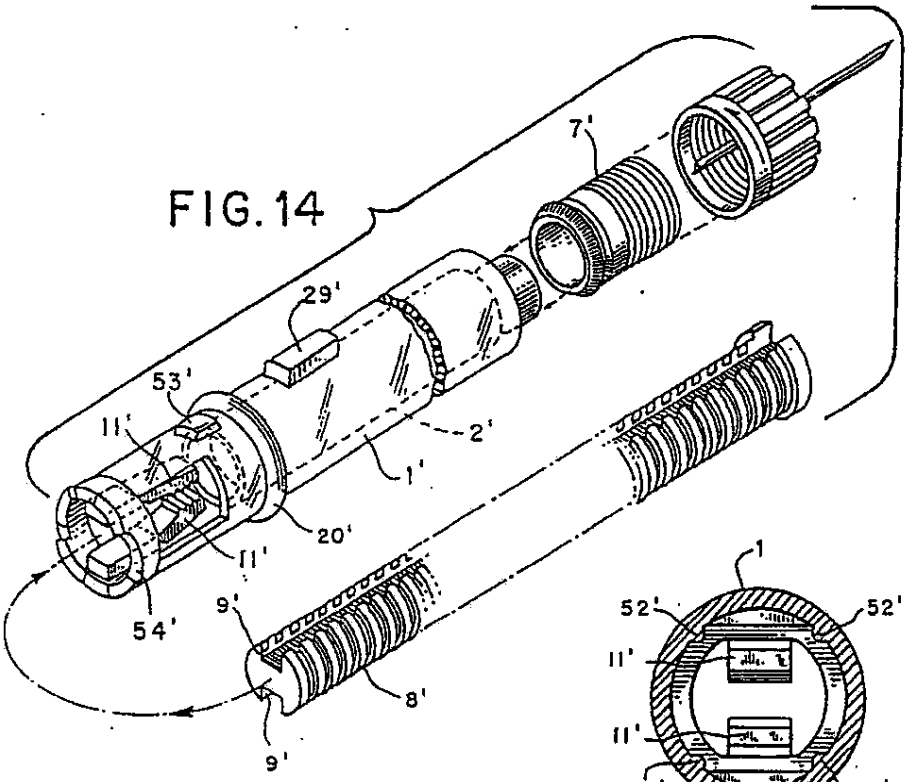

FIG. 16

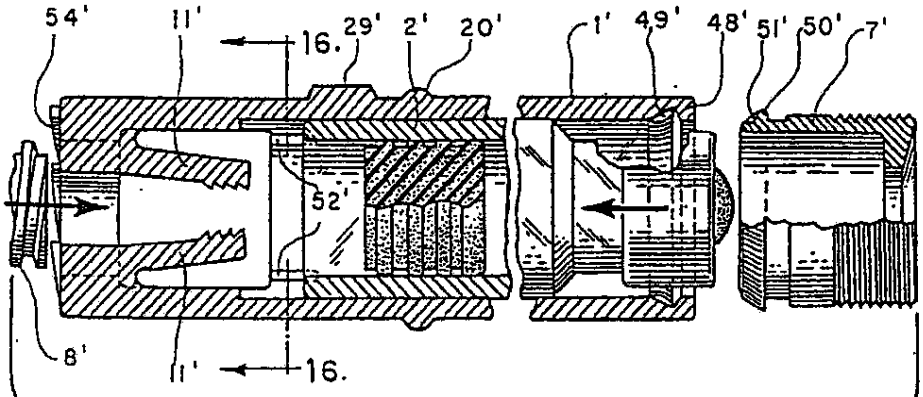

FIG. 15

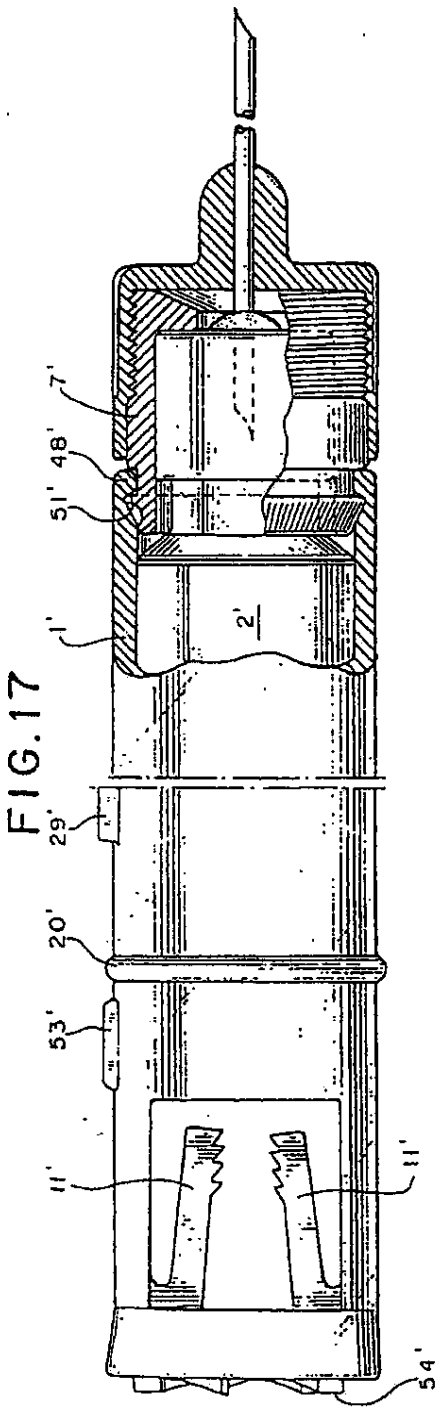

FIG.17

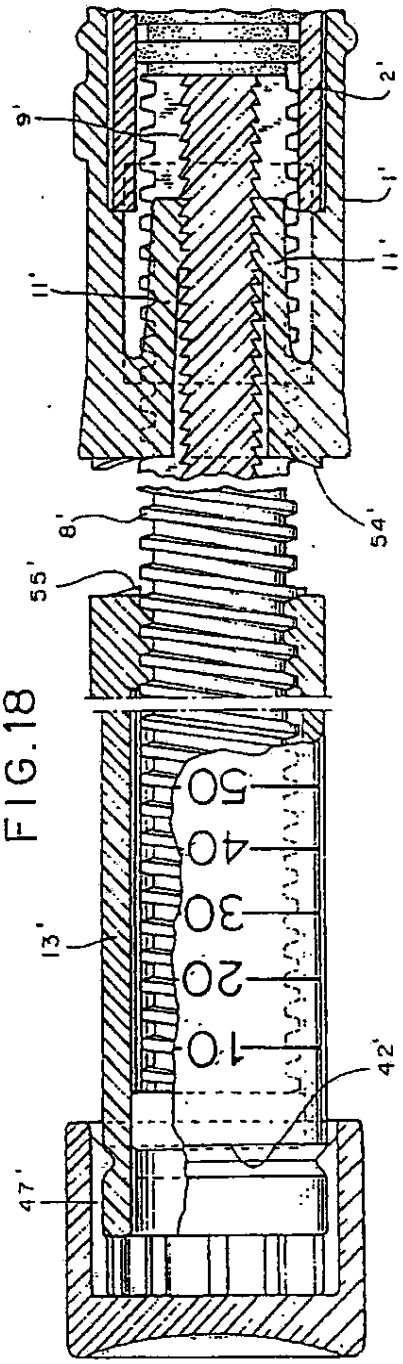

FIG.18

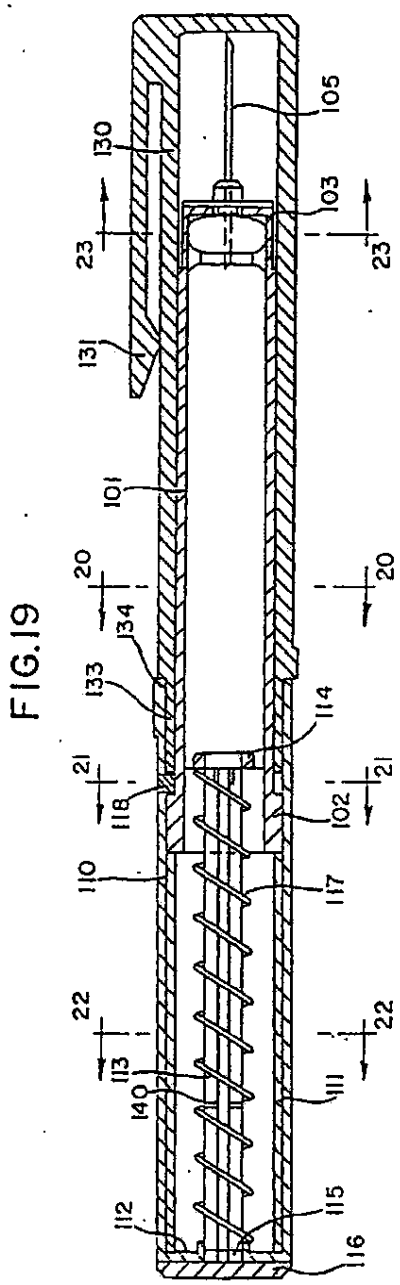
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FIG.19

FIG. 20

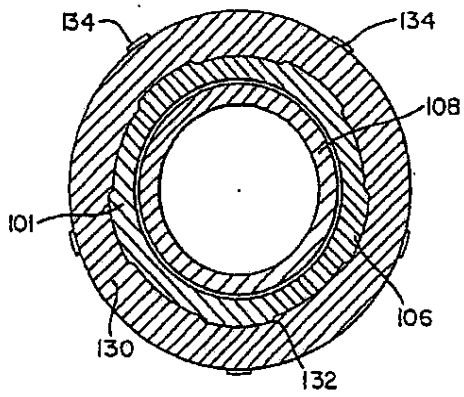


FIG. 21

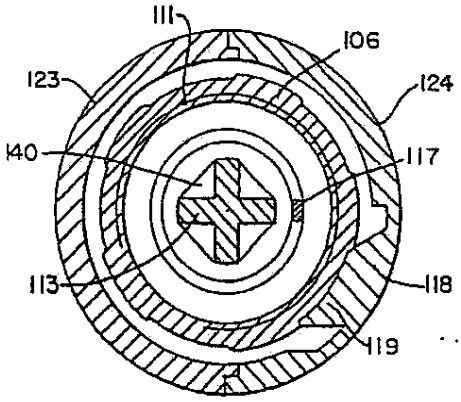


FIG. 22

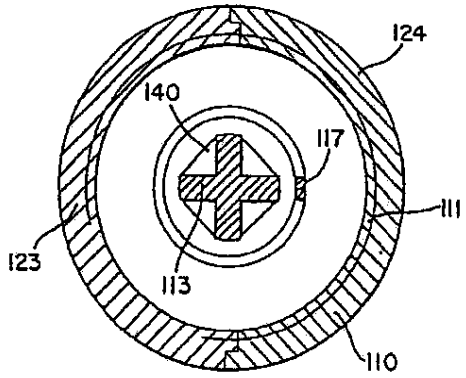
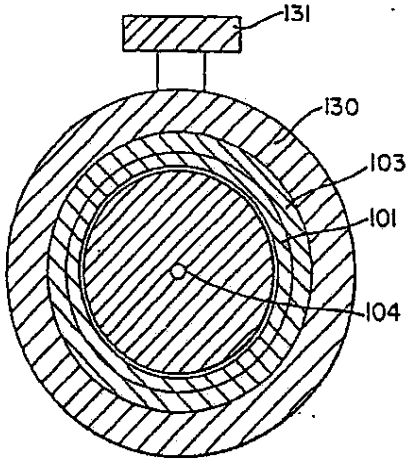


FIG. 23



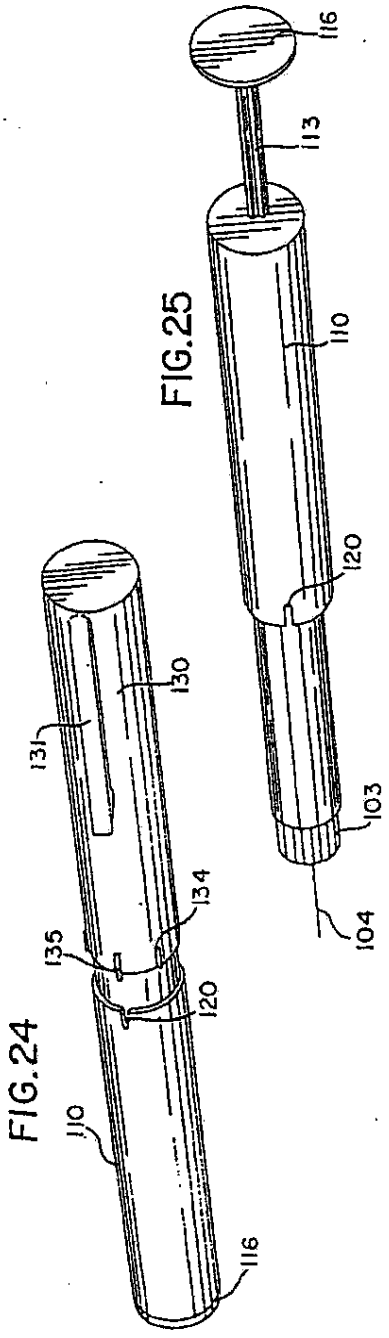


FIG.25

FIG.24

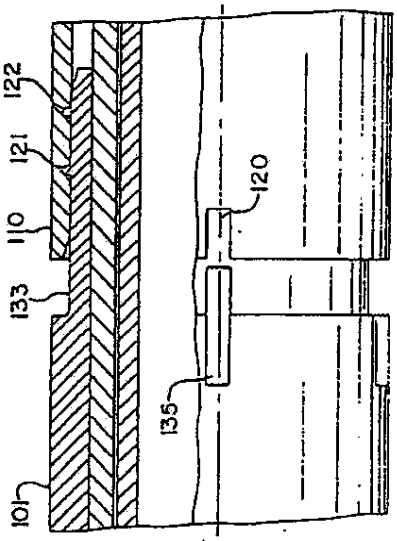


FIG.27

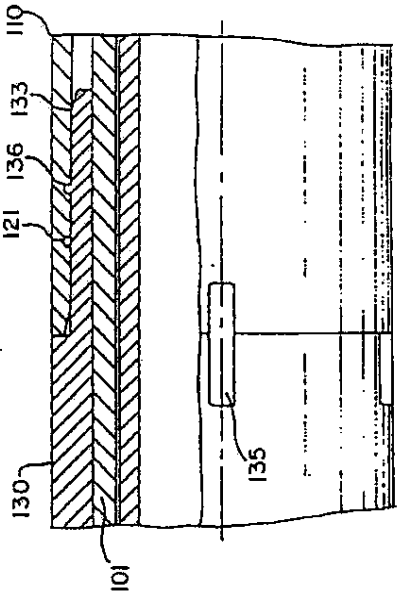


FIG.26

DISPOSABLE SYRINGE

TECHNICAL FIELD

This invention relates to a disposable syringe for injecting preset doses of a liquid contained in the syringe. The syringe of this invention is particularly but not exclusively applicable for delivering preset dosages of insulin, and the following description relates to a device for the injection of insulin solutions. However, it is to be understood that the syringe of this invention is also suitable for the injection of preset dosages of other liquids.

In particular, this invention relates to a syringe or dosage unit of the type that comprises first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, wherein the first housing element is adapted to receive a quantity of liquid and comprises means for mounting a liquid outlet needle in the front end thereof, and wherein the second housing element has a rear end situated opposite the front end of the first housing element.

BACKGROUND ART

Diabetics have to inject themselves repeatedly with insulin solution, and the volume of insulin solution to be injected may vary from injection to injection. For this reason, diabetics need syringes which allow them to inject successive measured dosages of the same or different preset volumes of insulin solution.

A wide variety of syringes have been proposed. For example, International Patent publication No. WO 82/02662 discloses a dose metering device for use with a syringe. The metering device utilizes a manually rotatable cap which axially moves the piston in the syringe. The volume delivered by the syringe is determined by the angular stroke of the cap. This device is not fully satisfactory for use by diabetics, because it requires two hands to hold the syringe and rotate the cap. For this reason, a diabetic cannot use this device to inject insulin into a skin fold, as recommended by many physicians.

Another drawback of the above-mentioned dose metering device is that production costs are so high that in practice it must be re-used. This necessitates replacement of the syringe or at least a cartridge with a new one. During the reloading operation, dust or other contaminants may be introduced into the metering device and this may adversely affect the operation of the metering device. Furthermore, there are more and more different commercially available insulin preparations, and therefore there is an increasing risk that a patient may insert a syringe or cartridge containing an insulin preparation other than the required one. Furthermore, reloading requires a series of operations which although not complicated may yet be troublesome for the patient.

It is therefore an object of this invention to provide a syringe that is so simple and inexpensive that it can be discarded after use.

Another object of this invention is to provide a syringe capable of delivering a number of accurate preset doses without reloading.

A further object of the invention is to provide a syringe which can be used for a single handed operation, with preadjustment of the total quantity to be injected.

A further object of the invention is to provide a syringe of such dimensions that it can be carried in a pocket like a writing pen.

Yet another object of this invention is to provide a dosage unit that maintains a constant length in use.

SUMMARY OF THE INVENTION

According to a first aspect of this invention, a disposable syringe of the type described above comprises a piston rod disposed in the second housing element to move axially therein. This piston rod comprises a rod element and a nut element. The rod element is coupled to the first housing element to move axially therein without relative rotation therebetween; and the nut element is threaded to the rod element for telescoping movement therewith and is configured to move axially in the second housing element without relative rotation therebetween. A pressure receiving element is mounted on the nut element, and the housing, rod, nut and pressure receiving elements all cooperate such that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and nut elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element. In this way, a measured quantity of the liquid is expressed from the needle when the pressure receiving element is moved back toward the second housing element.

Preferably, the nut element defines an axial scale along its length and is used in combination with the second housing element to gauge the dosage of liquid to be administered. As described below, the first and second housing elements may be arranged to rotate with respect to one another without axial movement therebetween such that the first and second housing elements maintain a substantially constant overall length as liquid is progressively dispensed through the needle.

The disposable syringe described below is easily preadjusted to the desired dose and quantity by rotating the two housing elements with respect to one another. This causes the nut element to move along the rod element and the pressure receiving element to be axially displaced. The indicator or scale connected to the nut element thereby moves with respect to the second housing element, and the scale can be used to measure the quantity of liquid that will be dispensed when the pressure receiving element is pushed back toward the second housing element. When the pressure receiving element is pushed back to its initial position, the nut element engages the rod element and the rod element is prevented from rotating relative to the first housing element. For this reason, axial movement of the nut element results in movement of the rod element. Preferably, a ratchet device is installed between the first housing element and the rod element to insure that the rod element cannot be retracted once it is pushed into the first housing element.

The following detailed description describes a number of other advantageous features of the invention. For example, the nut element preferably comprises at least one radially protruding, axially extending projection on the outside of the nut element which slides in an associated axially extending groove of the inner surface of the second housing element. Preferably, the nut element is shaped to limit axial movement of the nut element out of the second housing element beyond the predetermined limit, and in this way to prevent the dosage unit from being adjusted to deliver a potentially dangerously high

dose of liquid. In the preferred embodiment described below, the nut element and the indicator on the nut element are integrally formed together, thereby minimizing the total number of parts and the cost of the system. In this embodiment the nut element is substantially axially symmetrically shaped, and the pressure receiving element at the external end of the nut element has an outer diameter that corresponds to the outer diameter of the second housing element. As a result, the axial movement of the nut element towards the distal or rear end of the second housing element is stopped in a simple manner.

This embodiment utilizes a rod element that is prevented from rotating relative to the first housing element by means of a ratchet device. As discussed below, at least one and preferably two pawls are provided on the first housing element, and these pawls engage longitudinal grooves in the rod element, which are provided with a suitable toothed configuration to cooperate with the pawls.

According to a second feature of this invention, a disposable syringe or dosage unit, which may, for example, be of the type described above, includes a protective cap that is removably mounted over the front end of the first housing element to protect the needle. Means are provided for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

Preferably, the protective cap is configured to receive the first housing element such that a front portion of the second housing element substantially abuts a rear portion of the protective cap when the protective cap is mounted in place on the first housing element. In the preferred embodiment described below, the abutting ends of the cap and the second housing element together comprise a scale for measuring relative rotation of the protective cap with respect to the second housing element. This scale allows the rotational position of the cap with respect to the second housing element, and therefore the dose to be injected, to be gauged precisely. The scale formed at the abutting ends of the cap and the second housing element indicates the rotational position of the cap in fractions of a full rotation, while the measuring scale associated with the nut element described above indicates the number of full rotations of the cap with respect to the second housing element.

In the preferred embodiment described below, the cap may be releasably engaged with the first housing element at any one of a number discrete rotational positions, and a plurality of detents are provided at corresponding increments of rotation of the first housing element with respect to the second housing element. With this arrangement it is always possible to situate the measuring scale portion of the cap opposite a fixed zero on the second housing element such that this zero position forms the basis for measuring rotation of the cap with respect to the second housing element. This is possible regardless of the detent position of the first housing element with respect to the second element, and it provides the important advantage that the user of the syringe is provided with a clear zero position at the start of each adjustment. This feature instills confidence in the user that the desired dosage has in fact been selected.

The invention itself, together with further objects and attendant advantages, will best be understood by reference to the following detailed description, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first preferred embodiment of a dosage unit according to the invention, said dosage unit being ready for injection of a predetermined quantity of liquid.

FIG. 2 is an axial sectional view of the dosage unit of FIG. 1 before the adjustment of a predetermined dosing quantity.

FIG. 3 is an axial sectional view through the dosage unit of FIG. 1.

FIG. 4 is a sectional view taken along line 4—4 of FIG. 3.

FIG. 5 is a sectional view taken along line 5—5 of FIG. 3.

FIG. 6 is a perspective view of an embodiment of an indicator integrally formed with an associated nut member, with portions removed for the sake of clarity.

FIG. 7 is an axial sectional view of the nut member of FIG. 6.

FIG. 8 is a perspective view of a second preferred embodiment of a dosage unit or disposable syringe according to this invention.

FIG. 9 is a partial view of the syringe FIG. 8, showing the cap positioned to allow rotation of the cap with respect to the second housing element of the syringe.

FIG. 10 is a view corresponding to FIG. 9 showing the cap seated in its zero position against the second housing element.

FIG. 11 is a longitudinal sectional view taken along line 11—11 of FIG. 8.

FIG. 12 is a cross-sectional view taken along line 12—12 of FIG. 11.

FIG. 13 is a cross-sectional view taken along line 13—13 of FIG. 11.

FIG. 14 is an exploded perspective view of components of the syringe of FIG. 8.

FIG. 15 is an exploded breakaway longitudinal sectional view of selected components of FIG. 14.

FIG. 16 is a cross-sectional view taken along line 16—16 of FIG. 15.

FIG. 17 is a side view in partial cut-away of selected components of FIG. 14 in the assembled position.

FIG. 18 is a longitudinal sectional view of components of the syringe of FIG. 8.

FIG. 19 is a longitudinal sectional view of a third embodiment of a dosage unit according to this invention.

FIG. 20 is a cross-sectional view taken along the line 20—20 of FIG. 19.

FIG. 21 is a cross-sectional view taken along the line 21—21 of FIG. 19.

FIG. 22 is a cross-sectional view taken along the line 22—22 of FIG. 19.

FIG. 23 is a cross-sectional view taken along the line 23—23 of FIG. 19.

FIG. 24 is a perspective view of the syringe of FIG. 19, showing the cap partially removed.

FIG. 25 is a perspective view of the syringe of FIG. 19, showing the cap fully removed.

FIG. 26 is a partial longitudinal sectional view of the syringe of FIG. 19, showing the cap fully inserted into the second housing element.

FIG. 27 is a view corresponding to FIG. 26 showing the cap partially removed from the second housing element.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1–7, 8–18 and 19–27 relate to first, second, and third embodiments of this invention, respectively. The first and second embodiments embody both aspects of the invention described above, while the third embodiment embodies only the second aspect of the invention.

Turning to FIGS. 1–7, the first embodiment comprises a first housing element or casing 1 for a cartridge 2 containing a liquid 3. The cartridge 2 comprises a piston 4 pressing the liquid 3 out through a needle 5 inserted in the opposite end, said needle being secured to the casing 1 in a generally known manner by screwing on of a cup-shaped cap 6. As indicated in FIGS. 2 and 3, the cartridge 2 can be retained in the casing by means of a retaining cap 7 optionally secured to the casing by a snapping effect. The retaining cap 7 allows introduction of a protruding end of the needle 5, said end optionally extending into the interior of the cartridge. This introduction and insertion of the needle 5 is preferably carried out during the screwing on of the needle-carrying cap 6 onto the retaining cap 7 of the casing 1.

At the end opposite the needle 5 the dosage unit comprises a piston rod member 8 driving the piston 4 in the cartridge 2. This piston rod member 8 comprises a longitudinal groove 9 provided in the bottom with transverse barbs 10, and the groove 9 is serrated when seen in a longitudinal section (FIG. 3). These barbs cooperate with a pawl 11 formed on the casing 1. The pawl 11 is provided with barbs which cooperate with the barbs 10 on the piston rod member 8. These barbs 10 and the pawl 11 are shaped so as only to allow displacement of the piston rod member 8 towards the piston 4 of the cartridge and to prevent displacement in the opposite direction. As indicated in FIG. 5, the pawl 11 and the groove 9 are of such a width that their cooperation prevents the piston rod member 8 from rotating relative to the casing 1.

The piston rod member 8 further comprises a thread 12 shaped along its external periphery, and a nut member 13 is screwed onto the thread 12. On the outside the nut member 13 comprises radially protruding projections 14 and 15 extending axially along the outer side of the nut member 13 and received in corresponding respective grooves 16 and 17 (FIG. 4) in a surrounding sleeve-shaped adjustment means or second housing element 18. At the end adjacent the casing 1 this adjustment means 18 comprises a circumferential groove 19 receiving a circumferential projection 20 on the casing 1. As a result the adjustment means 18 is rotatable with respect to the casing 1, yet it is prevented from moving axially.

The nut member 13 is integrally shaped with a tubular indicator 21 extending coaxially with the piston rod member 8 away from the casing 1 between the piston rod member 8 and the adjustment means 18. At the free end projecting outside the adjustment means 18, the indicator 21 comprises an end button or pressure receiving element 22 of substantially the same outer diameter as the adjustment means 18. As indicated in FIGS. 2 and 3, the nut member comprises a circumferential abutment surface 23 at the transition to the tubular indicator. Correspondingly, the adjustment means 18 comprises an inner circumferential abutment surface 24, the abutment surface 23 on the nut member abutting the abutment surface 24 to provide a predetermined stop position as the nut member is displaced in the axial direction relative to the adjustment means 18. The grooves 16 and 17 shaped on the inner side of the adjustment means 18 are of such an extent that the nut member 13 can move freely in the axial direction relative to the adjustment means between the adjacent end of the casing 1 and the inner abutment surface 24 on the adjustment means 18.

The dosage unit also includes a removable cap 25 protecting the needle 5 when the dosage unit is not used. This cap is of such an axial extent that when mounted, its free rim 26 is situated adjacent the adjustment means 18. Axial recesses or grooves are provided close to the free rim 26 of the cap 25, said recesses being situated symmetrically with the same mutual angular separation from one another along the inner side of the cap. These recesses are indicated by the reference numerals 27 and 28 in FIGS. 2 and 3 and receive correspondingly shaped protruding projections 29 and 30, respectively, on the outer side of the casing 1. In this manner the cap can always be situated in a predetermined rotational position relative to the periphery of the casing 1. Preferably the projections 29 and 30 on the casing 1 are shaped to snap into the recesses 27 and 28 on the cap 25.

As shown in FIG. 5, the casing 1 is provided with axially shaped grooves 31, 32, 33, 34 and 35 along its circumference. These grooves are situated with the same mutual angular spacing as the grooves or recesses 27 and 28 on the inner side of the cap 25. These grooves 31–35 on the outer side of the casing 1 cooperate with a projection 36 on the adjustment means 18 which projects inwardly. The grooves 31–35 and the projection 36 are shaped such that the adjustment means 18 can readily be rotated relative to the casing 1 by a user. The projection 36 cooperates with the grooves to releasably hold the casing 1 at any one of five detent positions with respect to the adjustment means, and to provide an audible click as the casing 1 is advanced from one detent position to the next.

A scale is provided on the outer side of the adjustment means 18 at the end adjacent the cap 25 (FIG. 1). This scale comprises a platform 37 with the number 0 thereon. Correspondingly, the cap 25 comprises a knob 38 to be situated opposite the platform 37. The arbitrary positioning of the cap 25 along the circumference of the casing and the corresponding positioning of the adjustment means 18 also relative to the circumference of the casing 1 renders it possible for the user always to be able to situate the knob 38 opposite the platform 37 before the adjustment is initiated.

The dosage unit of FIGS. 1–5 operates in the following manner. Upon positioning of the knob 38 opposite the platform 37 of the adjustment means 18, the desired dosing quantity is set by turning the cap 25 and therefore the casing 1 relative to the adjustment means 18. As a result, the nut member 13 is forced to follow the rotation, the abutment of said nut member 13 against the end of the casing 1 preventing a turning of the adjustment means 18 in the incorrect direction. The rotation of the nut member 13 relative to the piston rod member 8 moves the nut member 13 away from the cartridge by the thread 12, and the indicator moves axially away from the free end of the adjustment means 18. As a result, a coarse measuring scale 39 appears on the outside of the indicator 21. This scale can be configured to

indicate the dosing quantity in question in full turns of the adjustment means 18 relative to the knob 38 on the cap 25, while the scale 40 on the end of the adjustment means adjacent the cap 25 indicates the dosing quantity by portions of a full rotation of the adjustment means 18 relative to the knob 38.

When the desired dosing quantity has been set, the turning of the adjustment means 18 is stopped at a suitable location defined by the inner projection 36 being received in one of the grooves 31–35 on the outside of the casing 1. Subsequently, the user removes the cap 25 and positions the dosage unit at the desired location to insert the needle 5. Then the indicator 21 is forced back into the adjustment means 18 by pressing on the end button 22 until this movement is stopped by the abutment of the nut member 13 against the end of the casing 1 or the abutment of the end button 22 against the adjacent end of the adjustment means 18. The pawl 11 prevents the piston rod member 8 from rotating, and the displacement of the indicator 21 therefore causes displacement of the piston rod member by a corresponding distance, whereby the piston of the cartridge is pressed towards the outlet end of the cartridge. As a result, a quantity of liquid is pressed out of the cartridge, said quantity corresponding to the quantity measured on the measuring scales. After completion of the injection of liquid, the dosage unit is of the same length as before the preadjustment and therefore it maintains an acceptable, uniform appearance.

A suitable choice of material allows the casing 1 to be transparent, whereby the user can always see whether liquid is left in the cartridge. The cap 25 ensures simultaneously that the contents of the cartridge are protected against sunlight. The various parts of the dosage unit are advantageously made of plastics by injection molding and are relatively easy to manufacture.

FIGS. 6 and 7 illustrate an alternate form of the indicator 21 and the associated nut member 13. On the outside this indicator comprises a protrusion 41 received in a corresponding groove on the inside of the adjustment means 18. At the end opposite the protrusion 41, a circumferential groove 42 is provided for the fastening of a loose end knob (not shown) shaped like the end knob 22.

Many modifications can be made to the first embodiment without thereby deviating from the scope of the invention. The piston rod member may, for instance, be of different cross sections depending on the shape of the ratchet device, and the piston rod member may be prevented from rotating by a suitable shaping of the opening through which the piston rod member passes into the casing 1. Mating teeth may be provided on the end of the nut member 13 adjacent the casing 1 as well as on the abutting end of the casing 1. These teeth are preferably shaped as cooperating barbs preventing a mutual rotation of the casing 1 and the nut member towards a stronger tension. These barbs allow a slight turning in the opposite direction.

As illustrated in FIG. 1, the cap 25 is of a non-circular cross section at the end opposite the adjustment means 18 when said cap is secured on the dosage unit. In this manner it is easy to handle the cap during the mounting procedure. Furthermore, a clip 43 is provided which secures the dosage unit to a pocket in a manner similar to a fountain pen.

The second preferred embodiment of FIGS. 8–19 is similar in many respects to the first preferred embodiment described above. In view of these similarities, corresponding elements in the second embodiment are identified with the same reference numeral as in the first embodiment, with the addition of a prime. Points of similarity between the two embodiments will not be repeated, and the following discussion will focus on the differences between these embodiments.

As best shown in FIGS. 8, 9 and 10, the illustrated disposable syringe includes a removable cap 25' which fits against the second housing element 18'. The second housing element 18' defines a projecting element 44', and the cap 25' defines a mating recess 45'. FIG. 10 shows the way in which the projecting element 44' fits within the recess 45' to define a zero position when the cap 25' is moved against the second housing element 18'. When it is desired to rotate the cap 25' with respect to the second housing element 18', the cap 25' is moved to the position shown in FIG. 9, in which the projecting element 44' is positioned outside of the recess 45', thereby allowing rotation.

The nut element 13' is quite similar to that shown in FIGS. 6 and 7, and the second housing element 18' includes an internal rib 46' that cooperates with the protrusion 41' to define a stop position, beyond which the nut element 13' cannot move. The pressure receiving element 22' defines an array of internal ribs 47' on its internal surfaces, and these ribs 47' are configured to snap into and to engage the circumferential groove 42' in the nut element 13'. These ribs 47' are best shown in FIGS. 11 and 18. In this way assembly of the syringe is facilitated, without requiring adhesives of any type.

FIGS. 11 and 12 show the manner in which the first housing element 1' includes a projection 29' that is shaped to fit into any one of five equally spaced recesses 27' in the cap 25'.

As best shown in FIGS. 14, 15 and 17, the first housing element 1' defines a circumferential lip 48' at its forward end, as well as a circumferential array of lugs 49'. The retaining cap 7' defines a mating groove 50', and a circumferential array of mating recesses 51'. When the retaining cap 7' is snapped in place on the first housing element 1' (FIG. 17), the lip 48' fits within the groove 50' to hold the retaining cap 7' securely in place axially. Similarly, the lugs 49' engage respective ones of the recesses 51' to prevent relative rotation between the retaining cap 7' and the first housing element 1'.

As best shown in FIGS. 14, 15 and 16, the piston rod element 8' defines two diametrically opposed longitudinal grooves 9', and the first housing element 1' includes two diametrically opposed pawls 11', each shaped to fit into a respective one of the grooves 9' to prevent relative rotation between the piston rod element 8' and the first housing element 1'. Ribs 52' (FIGS. 15 and 16) are provided to engage the cartridge 2' frictionally.

As best shown in FIGS. 11 and 14, the first housing element 1' also defines a raised lug 53' which cooperates with five equally spaced grooves in the second housing element 18' (not shown) to define five detented rotational positions of the first housing element 1' with respect to the second housing element 18'. As best shown in FIGS. 14 and 18, the first housing element 1' and the nut element 13' define respective ramps 54', 55'. These ramps are oriented to prevent relative rotation in a selected direction between the first housing element 1' and the nut element 13' when the ramps 54', 55' engage one another so as to prevent excessive stresses on the pawls 11'.

As mentioned above, the operation of the embodiment of FIGS. 8–18 is quite similar to that of the first

preferred embodiment, and will not be described again here.

In the first and second embodiments described above, the piston rod is in each case a two-part assembly made up of a piston rod element and a nut element. However, this is not essential for all syringes using the protective cap of this invention, and the third preferred embodiment shown in FIGS. 19–27 includes a one-piece piston rod.

The disposable syringe illustrated in FIGS. 19–27 comprises a first housing element 101 shaped to receive a liquid filled cartridge (see FIGS. 20, 23). The liquid filled cartridge is preferably of a conventional type and comprises at its front end a rubber membrane, which can be pierced by a needle, and at its rear end an axially displaceable piston. The rear end of the first housing element 101 comprises a relatively short external thread 102 capable of cooperating with an internal thread in a second housing element described below.

A needle assembly, comprising a hub 103, a double pointed needle 104 and internal threads 105, is screwed onto the front end of the first housing element 101. This causes the rear end of the needle 104 to penetrate the rubber membrane of the liquid filled cartridge when the latter is pressed into position against the front end of the first housing element 101.

The first housing element 101 is preferably made of a transparent plastic material, and it comprises five equally spaced longitudinally extending ribs 106 (see FIGS. 20 and 21). The disposable syringe further includes a second housing element 110 surrounding at least the rear end of the first housing element 101 and having an internal thread 111 that cooperates with the external thread 102 on the first housing element 101. The mating threads on the first and second housing elements 101, 110 are configured such that clockwise rotation of the first housing element 101 with respect to the second housing element 110 causes the first housing element 101 to be axially displaced towards the rear end of the second housing element 110. The second housing element 110 includes a rear end wall 112, and the syringe further includes a central, axially displaceable piston rod 113. The front end of the piston rod 113 comprises a collar 114, and the rear end of the piston rod 113 extends through an opening 115 in the end wall 112 and terminates in a pressure receiving element 116. A coil spring 117 surrounds the piston rod 113 and is tensioned between the collar 114 and the interior side of the end wall 112. This coil spring 117 tends to press the front end of the piston rod 113 against the piston of the cartridge located within the first housing element 101, and to maintain the pressure receiving element 116 in contact with the exterior of the end wall 112.

The second housing element 110 also comprises a combined pawl and click mechanism 118. This mechanism 118 extends into the interior of the second housing element 110 and includes a projection 119 having the shape of a saw tooth in contact with the exterior surface of the first housing element 101 and in particular the ribs 106 in such a manner that a counterclockwise rotation of the first housing element 101 relative to the second housing element 110 requires a predetermined force which is greater than the force required to cause clockwise rotation. The mechanism 118 is resiliently connected with the second housing element 110 in such a manner that a click is produced when the projection 119 slides over a rib 106 on the exterior of the first housing element 101.

The second housing element 110 includes at its front end an axially extending recess 120, which cooperates with an axially extending rib provided on a protecting cap described below. The second housing element 110 also defines two axially spaced annular grooves 121, 122 which are positioned on the interior side of the second housing element 110 near the front end. The grooves 121, 122 cooperate with an annular locking ring provided on the protecting cap described below.

As shown in FIGS. 21 and 22, the second housing element 110 is composed of two parts 123, 124 which are interconnected with one another at a plane that extends axially of the second housing element 110.

The disposable syringe further includes a protecting cap 130 which carries at its front end a clip 131. The protecting cap 130 defines at an internal surface five axially extending grooves 132, shaped to receive the ribs 106 provided on the exterior surface of the first housing element 101. The mating ribs 106 and grooves 132 form splines that rotationally engage the protecting cap 130 with the first housing element 101. For this reason, when the protecting cap 130 is positioned over the first housing element 101, rotation of the protecting cap 130 automatically causes a similar rotation of the first housing element 101.

The rear end of the protecting cap 130 includes a section 133 of a reduced diameter sized to fit within the front end of the second housing element 110. At the rear end of the portion of the protecting cap 130 having the full diameter of the protecting cap 130, there are provided a number of axially extending ribs 134, and one of these ribs 135 is shaped as a projection which extends into the section 133 of reduced diameter. The projecting rib 135 is shaped to be inserted into the recess 120 so as to prevent relative rotation between the protecting cap 130 and the second housing element 110.

The reduced diameter section 133 defines an external annular locking ring 136 that is shaped to fit into either one of the grooves 121 or 122 on the interior surface of the second housing element 110 (FIGS. 26 and 27).

When delivered to the patient the syringe of FIGS. 19 through 27 is loaded with a liquid filled cartridge, and the protecting cap 130 is inserted in the second housing element 110 with the projecting rib 135 on the protecting cap 130 inserted into the recess 120 in the second housing element 110. In this position, the annular rib 136 is located in the groove 122 (FIG. 26) and the protecting cap 130 is prevented from rotating relative to the second housing element 110.

Before setting the dose to be injected, the patient must axially displace the protecting cap 130 relative to the first housing element 101, preferably to a position in which the annular rib 36 is located in the groove 121 (FIG. 27). At this point, the patient is free to rotate the protecting cap 130 and the first housing element 101 to set the dose. By using the recess 120 as the zero point, the patient can select a desired dose by rotating the protecting cap 130 over an angle corresponding to a given number of the ribs 134 on the exterior surface of the protecting cap 130. Rotation of the first housing element 101 will cause the piston rod 113 to be axially displaced towards the rear end of the second housing element 110, thus axially displacing the pressure receiving element 116 from the exterior side of the end wall 112. After the desired dosage has been selected, the protecting cap 130 is removed and the syringe is now prepared for an injection (FIG. 25).

The injection is effected by depressing the pressure receiving element 116. Such a depression will cause the piston of the cartridge to be axially moved towards the front end of the syringe, thereby delivering the desired preset dosage of liquid from the tip of the needle 104. After the injection has been completed, the protecting cap 130 is reinserted on the end of the housing 101 with the rib 135 located in the recess 120, and the syringe is again ready for presenting an injection of another preset dosage of liquid.

The piston rod 113 defines stop members 140 which cooperate with the interior surface of the end wall 112 if the piston rod 113 is axially displaced over a distance which is longer than acceptable. In this way, the stop members prevent the selection of a dosage that exceeds a predetermined value.

All three embodiments described above are adapted for use with a liquid filled cartridge. This is convenient for many applications, because the material for the first housing element can be chosen without concern for possible adverse reaction with the solution to be injected. However, for some applications, it may be preferable to eliminate the cartridge and use the first housing element with a suitable piston to contain the solution directly.

We claim:

1. In a disposable syringe for injecting a number of measured doses of a liquid, of the type comprising first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, said first housing element adapted to receive a quantity of liquid and comprising means for mounting a liquid outlet needle at a front end thereof, said second housing element having a rear end situated opposite the front end of the first housing element, the improvement comprising:

a piston rod disposed in the second housing element to move axially therein, said piston rod comprising a rod element and a nut element, said rod element coupled to the first housing element to move axially therein without relative rotation therewith, said nut element threaded to the rod element for telescoping movement therewith and configured to move axially in the second housing element without relative rotation therein; and

a pressure receiving element on the nut element;

said housing, rod, nut and pressure receiving elements cooperating such that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and nut elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element such that a measured quantity of liquid is expressed from the needle when the pressure receiving element is moved back toward the second housing element.

2. The invention of claim 1 wherein the first and second housing elements are coupled together for rotation without axial displacement therebetween.

3. The invention of claim 1 wherein the pressure receiving element defines a first stop surface that limits travel of the nut element inwardly, towards the first housing element.

4. The invention of claim 2 wherein the nut element defines an axially oriented scale positioned to indicate the axial position of the nut element with respect to the second housing element.

5. The invention of claim 4 wherein the scale is integrally formed on the nut element.

6. The invention of claim 1 wherein the first housing element is configured to receive a cartridge having a pierceable diaphragm at a front end thereof, a slideable piston at a rear end thereof, and containing the quantity of liquid.

7. The invention of claim 2 wherein the nut element defines at least one radially protruding, axially extending projection on an exterior portion thereof, and wherein the projection is received in an axially extending groove in an inner portion of the second housing element.

8. The invention of claim 1 wherein the nut element comprises a second stop surface configured to contact the second housing element to limit axial movement of the nut element out of the second housing element.

9. The invention of claim 1 wherein the nut element and the pressure receiving element are substantially axially symmetrically shaped, and wherein the pressure receiving element defines an outer diameter substantially equal to that of the second housing element.

10. The invention of claim 1 further comprising

a removable protective cap configured to receive the first housing element and substantially abut the second housing element while mounted on the first housing element; and

means for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

11. The invention of claim 10 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise scale means for measuring relative rotation of the protective cap with respect to the second housing element.

12. The invention of claim 11 further comprising means for providing detents at selected rotational positions of the first housing element with respect to the second housing element.

13. The invention of claim 12 wherein the coupling means allows the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element to allow the protective cap to be oriented at a selected position with respect to the second housing element, regardless of the detent rotational position of the first housing element in the second housing element.

14. The invention of claim 10 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise interlocking means for defining a selected angular position of the protective cap with respect to the second housing element.

15. The invention of claim 14 wherein the interlocking means comprises a recess on the rear portion of the protective cap and a projection on the front portion of the second housing element, said projection shaped to fit into the recess to define the selected angular position.

16. The invention of claim 1 wherein the rod element defines at least one toothed axial groove, and wherein the rod element is coupled to the first housing element by at least one pawl that rides in the groove to prevent rotation of the rod element in the first housing element,

said pawl engaging the toothed groove to prevent retraction of the rod element.

17. The invention of claim 16 wherein the at least one groove in the rod element comprises two diametrically opposed grooves, and wherein the at least one pawl comprises two pawls, one riding in each of the grooves.

18. The invention of claim 16 wherein the liquid is contained in a cartridge and wherein the first housing element comprises a locking ring that snaps in place to lock the cartridge within the first housing element.

19. The invention of claim 18 wherein the locking ring mechanically interlocks with a mating portion of the first housing element to prevent rotation therebetween.

20. In a disposable syringe for injecting a number of measured doses of a liquid, of the type comprising first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, said first housing element adapted to receive a quantity of liquid and comprising means for mounting a liquid outlet needle at a front end thereof, said second housing element having a rear end situated opposite the front end of the first housing element, the improvement comprising:

a piston rod disposed in the second housing element to move axially therein, said piston rod comprising a piston actuating end and a force receiving end, said force receiving end positioned at the rear end of the second housing element when in an initial position;

means, responsive to relative rotation between the first and second housing elements, for causing the force receiving end of the piston rod to move away from the initial position to preset a dose to be delivered through the needle when the force receiving end is returned to the initial position;

a protective cap removably mounted over the front end of the first housing element to protect the needle; and

means for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

21. The invention of claim 20 wherein the protective cap is configured to receive the first housing element such that a front portion of the second housing element substantially abuts a rear portion of the protective cap when the protective cap is mounted in place over the first housing element.

22. The invention of claim 21 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise scale means for measuring relative rotation of the protective cap with respect to the second housing element.

23. The invention of claim 22 wherein the scale means comprises a circumferential scale on the rear portion of the protective cap and a marker on the front portion of the second housing element.

24. The invention of claim 20 wherein the releasably coupling means comprises a set of interengaging splines on the protective cap and the first housing element.

25. The invention of claim 24 wherein the splines are configured to allow the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element.

26. The invention of claim 21 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise interlocking means for defining a selected angular position of the protective cap with respect to the second housing element.

27. The invention of claim 26 wherein the interlocking means comprises a recess on the rear portion of the protective cap and a projection on the front portion of the second housing element, said projection shaped to fit into the recess to define the selected angular position.

28. The invention of claim 20 wherein the piston rod comprises a rod element and a nut element threadedly engaged with the rod element, and wherein the nut element is configured to move axially without rotating in the second housing element.

29. The invention of claim 28 further comprising ratchet means for preventing the rod element from retracting from the first housing element while allowing the rod element to move into the first housing element.

30. The invention of claim 20 wherein the first housing element is configured to receive a cartridge having a pierceable diaphragm at a front end thereof, a slideable piston at a rear end thereof, and containing the quantity of liquid.

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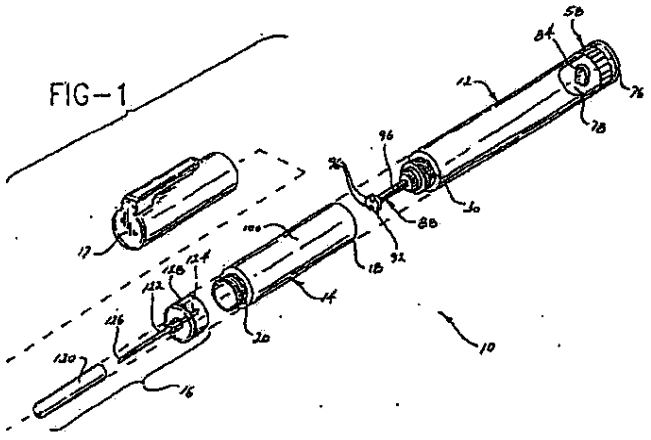
(54) Quick connect medication delivery pen

(57) A medication delivery pen is provided having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly. A portion of the pen body assembly projects into the cartridge holder assembly for driving the cartridge plunger distances that are selected in accordance with a desired dose of medication to be delivered. The cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, and the used cartridge holder assembly may be discarded and replaced.

FIG-1



EP 0 688 571 A1

BACKGROUND OF THE INVENTION

1. Field of the Invention

The subject invention relates to medication delivery pens having a disposable cartridge holder assembly and a reusable pen body assembly removably mounted to the cartridge holder assembly for delivering selected doses of medication.

2. Description of Related Art

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

The above described reusable medication delivery pen is effective and much more convenient for self-administration of medication than the typical hypodermic syringe and separate medication vial. However, the disassembly of the pen to remove empty medication vials and to insert new ones is an inconvenience. As a result, disposable pens have been developed. The prior art disposable medication delivery pen includes a vial of

insulin or other such medication permanently encapsulated therein. The patient need merely connect a double-ended needle cannula to the disposable pen for each administration of medication. The prior art disposable pen can be discarded when the supply of medication permanently encapsulated therein has been exhausted.

Disposable medication delivery pens offer certain conveniences to the patient who is required to self-administer medication. However, the dose selecting and driving mechanisms of prior art medication delivery pens are fairly complex devices that are costly to manufacture. Hence, a substantial cost penalty is associated with the convenience of using a disposable medication delivery pen.

SUMMARY OF THE INVENTION

The subject invention relates to a medication delivery pen having a disposable medication cartridge assembly that is selectively engageable with and disengageable from a reusable pen body assembly. The disposable medication cartridge assembly is an elongate generally cylindrical structure having opposed proximal and distal ends. The distal end of the disposable medication cartridge assembly includes needle mounting means for securely but releasably receiving a needle cannula assembly. The distal end may be characterized by a pierceable elastomeric seal that may be repeatedly and resealable pierced by the proximal end of a double-ended needle cannula. The proximal end of the disposable medication cartridge assembly includes body mounting means for securely but releasably mounting the disposable medication cartridge assembly to the reusable pen body assembly. The body mounting means may comprise an array of threads extending distally from the proximal end of the disposable medication cartridge assembly.

The disposable medication cartridge assembly further includes plunger means slidably disposed in fluid tight engagement therein. The plunger means may initially be disposed in a proximal position within the medication cartridge assembly and may be moved in a distal direction by a driver projecting from the pen body assembly. The disposable medication cartridge assembly further comprise anti-rotation means for preventing rotation of the driver.

The reusable pen body assembly of the subject invention comprises an array of mounting threads to enable threaded engagement of the reusable pen body assembly and the disposable medication cartridge assembly. An actuator button may be rotatably mounted on the proximal end of the pen body assembly. Thus, axial forces exerted on the actuator button will cause the pen body assembly to threadedly engage the disposable medication cartridge assembly.

The pen body assembly further includes a lead screw for selectively engaging the plunger of the disposable cartridge assembly and for urging the plunger of the disposable cartridge assembly in a distal direction. At least a portion of the lead screw may have driving threads engaged with other portions of the pen body assembly. This threaded engagement may be operative to achieve axial movement of the lead screw in response to axial forces exerted on the rotatable actuator button. The driving threads may define the same pitch and the same direction of generation as the mounting threads of the pen body assembly. As will be explained in greater detail below, this feature of the medication delivery pen facilitates the quick connection of the pen body assembly to the disposable medication cartridge assembly, and further assures a virtually automatic return of the lead screw to a start position each time a new disposable medication cartridge assembly is mounted to the pen body assembly. The lead screw may further be engageable with the anti-rotation means of the disposable cartridge assembly. Thus, relative rotation between the lead screw means and the disposable cartridge assembly is substantially prevented.

The pen body assembly further comprises a dose setting means for establishing and precisely controlling the amount of medication to be delivered in response to each actuation of the actuator button. The dose setting means may be any of several structures as described in greater detail below.

A disposable cartridge assembly that is filled with medication may be mounted to the pen body assembly by merely aligning the lead screw with the proximal end of the disposable cartridge assembly and exerting an axial force on the rotatable actuator button. The initial response to forces on the actuator button will cause the lead screw to move in a proximal direction toward its starting position, while the remaining portions of the pen body assembly move distally toward the disposable vial assembly. Further forces exerted on the actuator button will cause the mounting means of the pen body to engage the mounting means of the disposable cartridge assembly. Continued axial forces on the actuator will cause the mounting threads to engage the disposable cartridge assembly and will continue the proximal movement of the driver. The pen body assembly will be fully but releasably engaged with the disposable cartridge assembly at the same time that the driver is at its proximal extreme position and in condition to begin delivering selected doses of medication from the pen. Doses of medication can be dispensed as

needed over time. The disposable cartridge assembly can be removed and discarded when the medication therein has been exhausted, and a new disposable medication cartridge assembly may be mounted to the pen body assembly as described above.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded perspective view of the medication delivery pen of the subject invention.

Fig. 2 is an exploded perspective view of the pen body assembly of the medication delivery pen shown in Fig. 1.

Fig. 3 is an end view of the housing of the pen body assembly.

Fig. 4 is a cross-sectional view of the nut taken along line 4-4 in Fig. 2.

Fig. 5 is a cross-sectional view of the insert taken along line 5-5 in Fig. 2.

Fig. 6 is an end elevational view of the cartridge holder assembly.

Fig. 7 is a longitudinal cross-sectional view of the pen in a first partly assembled condition.

Fig. 8 is a cross-sectional view similar to Fig. 7, and showing the pen in a second partly assembled condition.

Fig. 9 is a cross-sectional view similar to Figs. 7 and 8, and showing the pen in a fully assembled condition.

Fig. 10 is a cross-sectional view similar to Fig. 9, and showing the assembled pen in condition to deliver a selected dose of medication.

Fig. 11 is a cross-sectional view similar to Fig. 10 and showing the pen after delivery of the selected dose.

DETAILED DESCRIPTION

A medication delivery pen in accordance with the subject invention is identified generally by the numeral 10 in Figs. 1 and 7-11. Medication delivery pen 10 includes a reusable pen body assembly 12, a disposable cartridge assembly 14, a needle cannula assembly 16 and a cap 17. Cartridge assembly 14 includes opposed proximal and distal ends 18 and 20 respectively. Proximal end 18 of cartridge assembly 14 is dimensioned and configured to threadedly engage pen body assembly 12, as explained further herein. Distal end 20 of cartridge assembly 14 is configured to securely but releasably engage needle cannula assembly 16.

The preferred embodiment of reusable pen body assembly 12 is illustrated in greater detail in Fig. 2. It is understood, however, that variations from this preferred embodiment may be provided, and are considered to be within the scope of the subject invention. Reusable pen body assembly 12 includes a generally cylindrical housing 22 having opposed proximal and distal ends 24 and 26, and a substantially hollow throughbore 28 extending axially therethrough. An array of external threads 30 extends proximally from distal end 26 for threaded engagement with proximal end 18 of cartridge holder assembly 14. Portions of hollow throughbore 28 of housing 22 adjacent distal end 26 are characterized by an array of clutch teeth 32, shown in Fig. 3, molded therein. Proximal end 24 of housing 22 is characterized by a cut-out 33 formed therein for receiving a window insert 78, as shown in Fig. 5 and explained further herein.

Pen body assembly 12 further includes a nut 34 having opposed proximal and distal ends 36 and 38 respectively. Exterior surface regions of nut 34 between proximal and distal ends 36 and 38, shown in Fig. 4, define a plurality of longitudinally extending splines 39. Proximal end 36 of nut 34 is characterized by a plurality of longitudinally extending resilient fingers 40 with enlarged ends that enable snap engagement of nut 34 into other portions of pen body assembly 12 as explained further herein. Distal end 38 of nut 34 is radially enlarged to limit axial movement of nut 34 into distal end 26 of housing 22. Thus, nut 34 is axially constrained within housing 22. However, the dimensions and configurations of nut 34 and housing 22 permit free relative rotation therebetween.

Pen body assembly 12 further includes a clutch assembly 42 mounted therein. Clutch assembly 42 includes a proximal clutch 44, a distal clutch 46 and an annular spring 48 biasingly engaged therebetween. Proximal and distal clutches 44 and 46 each are configured for non-rotatable engagement over splines 39 of nut 34. Distal clutch 46 includes an array of distally facing saw teeth dimensioned, disposed and configured for engagement with teeth 32, shown in Fig. 3, on the interior of housing 22, such that distal clutch 46 can rotate only in one direction relative to housing 22. Proximal clutch 44 includes an array of proximally facing teeth which are also configured for unidirectional rotation as explained further herein.

Pen body assembly 12 further includes a generally cylindrical driver 50 having opposed proximal and distal ends 52 and 54. Driver 50 is slidably inserted into housing 22 of pen body assembly 12 such that distal end 54 of driver 50 is snap fit over the enlarged ends of resilient fingers 40 at proximal end 36 of nut 34. This snap fit engagement prevents axial movement between nut 34 and driver 50, but permits free relative rotational movement within housing 22. Distal end 54 of driver 50 is also characterized by an array of saw teeth 49 that engage with the saw teeth on proximal clutch 44. Outer surface regions of driver 50 are characterized by splines 56 extending radially outwardly

thereon and along a substantial portion of the length of driver 50.

Pen body assembly 12 further includes a dose knob 58 which is a hollow generally cylindrical structure having opposed proximal and distal ends 60 and 62 and opposed inner and outer surfaces 64 and 66. Inner surface 64 is characterized by longitudinally extending grooves 68 which are disposed and dimensioned for engagement with splines 56 on driver 50. More particularly, dose knob 58 is spline mounted over driver 50 within housing 22 of pen body assembly 12. Thus, axially extending grooves 68 in dose knob 58 engage splines 56 of driver 50 to prevent relative rotation therebetween, but permitting relative axial movement. Outer surface 66 of dose knob 58 is characterized by a groove 70 that includes a linear component 72 and a helical component 74, which connects opposed ends of linear component 72. Portions of outer surface 66 adjacent helical component 74 of groove 70 are provided with dosage indicia to define dose amounts corresponding to different positions along groove 70 as explained further herein. Proximal end 60 of dose knob 58 is characterized by a gnarled exterior surface to facilitate manipulation for setting a selected dose. An actuator button 76 is snapped in to engagement with proximal end 60 of dose knob 58 to permit relative rotation therebetween.

An insert 78, shown in Figs. 2 and 5, is snapped into engagement with cut-out 33 in the proximal end 24 of housing 22. Insert 78 includes opposed inner and outer surfaces 80 and 82 and a window 84 extending therebetween. Inner surface 80 of insert 78 includes a button 86 on an interior face which is dimensioned and disposed to engage in groove 70 of dose knob 58. Button 86 and window 84 are disposed to enable the indicia on dose knob 58 to be visible through window 84.

Pen body assembly 12 further includes a lead screw 88 with opposed proximal and distal ends 90 and 92 and an array of external threads 94. External threads 94 are characterized, however, by a pair of opposed axially extending grooves 96 which extend from distal end 92 substantially to the proximal end 90. Threads 94 are engaged in nut 34, such that proximal end 90 of lead screw 88 is within housing 22 and distal end 92 projects distally beyond housing 22. Threads 94 on lead screw 88 have exactly the same pitch and the same hand as threads 30 on distal end 26 of housing 22.

Pen body assembly 12 is assembled by placing nut 34 into housing 22 from distal end 26. Clutch assembly 42 then is mounted over splines 39 on nut 34. Driver 50 is then inserted into proximal end 24 of housing 22, and is urged sufficiently in a distal direction for snap fit engagement with nut 34. In this snapped engagement, the saw teeth of distal clutch 46 will be secured in engagement with teeth 32 of housing 22, and the saw teeth of proximal clutch 44 will be engaged with saw teeth 49 at distal end 54 of driver 50. Spring 48 will maintain constant selected pressure between these interengaged saw teeth. Insert 78 then is positioned over dose knob 58 such that button 86 of insert 78 is engaged in the axial return track 72 of groove 70 in dose knob 58. The temporarily assembled insert 78 and dose knob 58 then are urged into housing 22. Lead screw 88 then is threaded into nut 34, and actuator button 76 is snapped into engagement with proximal end 60 of dose knob 58.

Cartridge assembly 14, shown in Figs. 1 and 6-11, includes a molded housing 100 which extends from proximal end 18 to distal end 20 of cartridge assembly 14, as noted above. Housing 100 includes a mounting cavity 102 extending inwardly from proximal end 18. Mounting cavity 102 is characterized by an array of internal threads 104 for threaded engagement with external threads 30 on distal end 26 of housing 22. The distal end of mounting cavity 102 is defined by anti-rotation tabs 106 which are dimensioned to slidably engaged in slots 96 of lead screw 88. Thus, lead screw 88 can slidably move relative to anti-rotation tabs 106, but is prevented from rotating relative to tabs 106.

Cartridge holder assembly 14, as shown in Figs. 7-11, further includes a medication cartridge 108 securely retained in housing 100 between tabs 106 and distal end 20 of cartridge assembly 14. Medication cartridge 108 includes an open proximal end 110 and a distal end 112 having a pierceable elastomeric seal 114 securely mounted thereto. A cap 116 extends between housing 100 and cartridge 108 for securely and permanently holding medication cartridge 108 in housing 100. A plunger 118 is disposed in sliding fluid tight engagement in cartridge 108. As shown in Figs. 7-11, plunger 118 initially is disposed substantially adjacent proximal end 110 of medication cartridge 108. Portions of cartridge 108 between plunger 118 and seal 114 are filled with a medication 120, such as insulin.

Needle cannula assembly 16 includes a double ended needle cannula 122 having opposed proximal and distal points 124 and 126, respectively, and a lumen extending axially therebetween. A mounting hub 128 is engaged on needle cannula 122 and is removably engageable with cap 116 of cartridge holder assembly 14. The relative location of mounting hub 128 ensures that proximal point 124 of needle cannula 122 will pierce seal 114 when mounting hub 128 is engaged with cap 116. Needle cannula assembly 16 further includes a shield 130 removably mounted thereon for protecting against accidental needle sticks until immediately prior to use of pen 10.

As noted above, pen body assembly 12 is reusable, and cartridge holder assembly 14 is disposable. More particularly, cartridge 108 in cartridge holder assembly 14 will contain a volume of medication 120 sufficient for administration of several doses. After exhaustion of the medication 120, cartridge holder assembly 14 will be threadedly disengaged from pen body assembly 12 and discarded. A new cartridge holder assembly 14 may then be mounted to the reusable pen body assembly 12. To effect the mounting of a new cartridge holder assembly 14 to the reusable pen body assembly 12, the patient need merely align slots 96 at distal end 92 of lead screw 88 with tabs 106 at proximal end 18 of cartridge holder assembly 14. Distal end 92 of lead screw 88 is then advanced distally into cartridge holder assembly 14 until distal end 92 of lead screw 88 engages plunger 118, as shown in Fig. 7. Assembly continues by merely exerting axial forces on thumb swivel 76 and on cartridge holder assembly 14. Additionally, friction between plunger 118 and cartridge 108 and fluid forces exerted by medication 120 and seal 114 will prevent axial advancement of lead screw 88 beyond the position depicted in Fig. 9 during assembly. Additionally, the splined engagement of distal clutch 46 with nut 34 and the engagement of the teeth on distal clutch 46 with the corresponding teeth 32 on housing 22 prevents independent rotation of nut 34 during this initial mounting of reusable pen body assembly 12 with a new disposable cartridge assembly 14. Thus, axial forces exerted on thumb swivel 76 will cause cartridge housing 100 to threadedly advance along threads 94 of lead screw 88.

After sufficient axial advancement, threads 30 at distal end 26 of pen body housing 22 will engage internal threads 104 at proximal end 18 of cartridge holder assembly 14, as shown in Fig. 8. As noted above, external threads 30 at distal end 26 of housing 22 have exactly the same pitch and hand as threads 94 on lead screw 88. Hence, further axial forces exerted on thumb swivel 76 will cause the simultaneous threaded advancement of housing 22 along lead screw 88 and into cavity 102 at proximal end 18 of cartridge holder assembly 14. Thus, because of their identical pitches, lead screw 88 will move proximally relative to pen body housing 22, while pen body housing 22 and cartridge holder assembly 14 are approaching their fully seated and threaded condition depicted in Fig. 9.

The assembled reusable pen body assembly 12 and cartridge assembly 14 may be stored until a selected dose of medication is required. Just prior to use, a needle cannula assembly 16 may be threadedly engaged to distal end 20 of cartridge assembly 14. This threaded engagement will cause proximal tip 124 of needle cannula 122 to pierce seal 114 and provide communication with medication 120. Shield 130 may then be removed.

A desired dose of medication 120 may be set by rotating dose knob 58 until indicia corresponding to the desired dose appears in window 84 of insert 78. The engagement of button 86 on insert 78 in helical portion 74 of groove 70 in dose knob 58 will cause a threaded retraction of dose knob 58 relative to housing 22 of reusable pen body assembly 12. This threaded retraction of dose knob 58 will cause a simultaneous rotation of driver 50 splined thereto. However, nut 34 will not rotate because the saw teeth on distal clutch 46 and saw teeth 32 on interior portions of housing 22 are locked to prevent rotation in that direction. Proximal clutch 44 is splined to nut 34, and hence also will not turn. However, saw teeth 49 at distal end 54 of driver 50 are shaped to allow rotation relative to proximal clutch 44, but provide an audible click for each unit of medication in the selected dose. This is helpful for visually impaired patients who may be required to set doses and administer insulin or other medication to themselves. Annular spring 48 contributes to the engagement that provides these audible clicking sounds.

When the desired dose is set, as shown in Fig. 10, injection is achieved by merely pushing on actuator button 76. This causes dose knob 58 to turn about helix 74 relative to pen body housing 22, and driver 50 rotates through the same number of degrees. This rotation is opposite to the rotation generated by the dose setting procedure, and the rotational freedom of the clutch assembly 42 is reversed. Thus, as driver 50 turns the previously clicking proximal clutch 44 is locked to and turns with driver 50. This driving movement of proximal clutch 44 causes a corresponding rotational movement of nut 34 because of the splined engagement therebetween. Distal clutch 46 is now free to rotate against saw teeth 32 on housing 22, and makes an audible clicking indication during injection of medication.

Rotation of lead screw 88 is prevented by tabs 106 unitarily molded with housing 100 of cartridge holder assembly 14. Therefore, as nut 34 rotates under the driving action of proximal clutch 44 and driver 50, lead screw 88 will be advanced axially into cartridge holder assembly 14. This axial advancement of lead screw 88 causes distal end 92 thereof to urge plunger 118 distally into cartridge 108, and hence causes medication 120 to be injected through needle cannula 122. Injection will be terminated when proximal end 60 of dose knob 58 engages against proximal end 24 of pen body housing 22, as shown in Fig. 11.

Upon completion of the injection, needle cannula assembly 16 may be disengaged from car-

tridge holder assembly 14 and safely discarded. Cap 17 may be mounted over cartridge holder assembly 14, and pen 10 may be stored or carried in a convenient location until the next dose of medication is required. A subsequent dose of medication will be set in exactly the manner as described above. However, for such a subsequent dose, lead screw 88 and plunger 118 will be in a partly advanced position as a starting point. Dose setting and injections can be carried out until all of medication 120 has been used. Cartridge holder assembly 14 may then be threadedly disengaged from pen body assembly 12, and slidably separated from lead screw 88. The separated cartridge holder assembly may then be discarded and replaced as described above.

While the invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. In particular, the reusable pen body assembly may have other driving and/or clutch mechanisms. Additionally, different means for preventing and/or enabling rotation during the dose setting and injection phases may be provided. Similarly, other means for mounting needle cannula to the cartridge assembly may be provided. These various optional constructions will be apparent to those skilled in the art after having read the subject disclosure.

Claims

1. A medication delivery pen comprising:

a disposable medication-containing cartridge having a pierceably sealed distal end and an open proximal end having an array of threads, a plunger in sliding fluid tight engagement within said cartridge at a location distally of said array of threads;

a reusable pen body assembly having a housing with opposed proximal and distal ends, said distal end having an array of threads dimensioned and pitched for threaded engagement with said threads at said proximal end of said cartridge, a lead screw having a proximal end disposed in said housing, a distal end projecting beyond said distal end of said housing for selective engagement with said plunger, and threads extending between said proximal and distal ends of said lead screw and defining a pitch substantially equal to said pitch of said threads at said distal end of said pen body assembly, said pen body assembly further comprising driver means for moving said lead screw distally in said pen body assembly selected amounts, whereby said lead screw is movable in a proximal direction in said pen body assembly as said pen body assembly is threadedly moved in a distal direction into engagement with said cartridge.

2. The medication delivery pen of Claim 1, wherein said pen body assembly further includes an actuator button rotatably mounted on said driver means, such that axial forces exerted on said actuator button simultaneously generate movement of said lead screw in a proximal direction in said pen body assembly and threaded engagement of said pen body assembly distally into said cartridge.

3. The medication delivery pen of Claim 1, wherein said lead screw includes at least one anti-rotation groove extending axially therealong, said cartridge including tab means for slidably engaging in said anti-rotation groove of said lead screw for preventing relative rotation between said lead screw and said cartridge.

4. The medication delivery pen of Claim 3, wherein said cartridge includes a housing unitarily molded from a plastic material, said tab being a unitary portion of said housing.

5. The medication delivery pen of Claim 1, wherein said cartridge defines a mounting cavity adjacent said proximal end thereof, said threads of said cartridge defining internal threads in said mounting cavity, said distal end of said pen body assembly being dimensioned for threaded engagement in said mounting cavity of said cartridge.

6. The medication delivery pen of Claim 1, wherein said pen body assembly comprises dose setting means for defining specified distances of travel for said lead screw corresponding to selected doses of medication to be delivered.

7. The medication delivery pen of Claim 1, wherein said sealed end of said cartridge comprises a pierceable elastomeric seal, and wherein said cartridge further comprises needle mounting means adjacent said distal end of said cartridge, said medication delivery pen further comprising a needle cannula assembly having a hub selectively engageable with the mounting means of said cartridge and a double-ended needle having opposed proximal and distal points, said proximal point of said needle being dimensioned and disposed to pierce said seal upon engagement with said cartridge.

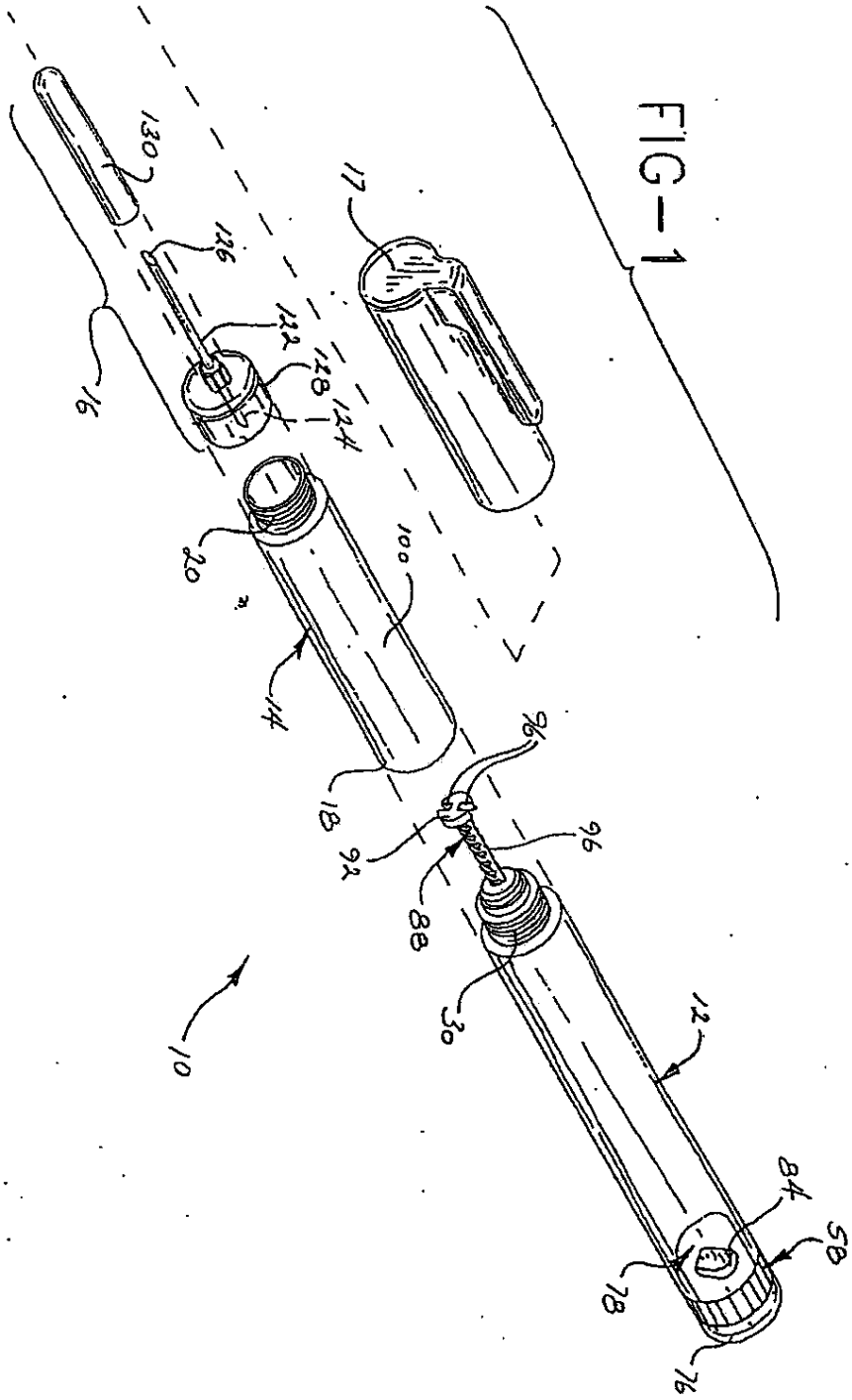
8. A reusable medication delivery pen system comprising:

a plurality of disposable cartridge holder assemblies, each said disposable cartridge holder assembly including an elongate cartridge housing having opposed proximal and distal ends, an elongate medication-containing cartridge mounted in said cartridge housing, said cartridge having a sealed distal end and an open proximal end, a plunger slidably disposed in fluid tight engagement in said cartridge, medication disposed in said cartridge intermediate said plunger and said seal, said proximal end of said housing of said cartridge holder assembly defining an array of threads;

a reusable pen body assembly having a pen body housing with opposed proximal and distal ends, said distal end of said pen body housing having an array of threads defining a pitch for threaded engagement with said threads at said proximal end of any of said cartridge housing, said pen body assembly having a driver selectively movable in proximal and distal directions in said pen body housing and dose setting means selectively adjustable for controlling amounts of movement of said driver, a lead screw having opposed proximal and distal ends, said distal end of said lead screw being selectively engageable with the plunger of any of said cartridge holder assemblies, said lead screw further comprising an array of external threads thereon threadedly engaged for rotation in said body housing, said threads on said lead screw defining a pitch substantially identical to said pitch of said threads on said distal end of said pen body housing, said lead screw being axially movable in said pen body housing in response to movement of said driver for selectively advancing said lead screw distances from said housing corresponding to selected doses of medication, whereby the substantially identical pitches of said threads on said lead screw and on said pen body housing enables said lead screw to move proximally in said body housing simultaneously with threaded engagement of said body housing with said cartridge holder housing.

9. The medication delivery pen system of Claim 8, further comprising a plurality of needle cannula assemblies, each said needle cannula assembly being selectively engageable and disengageable from each of said respective cartridge holder assemblies.

10. The medication delivery pen system of Claim 8, wherein the lead screw of said reusable pen body assembly includes a longitudinally extending groove therein, and wherein each said cartridge housing includes a tab for slidably engaging the lead screw, whereby said tabs prevent relative rotation between said lead screw and said cartridge holder assembly.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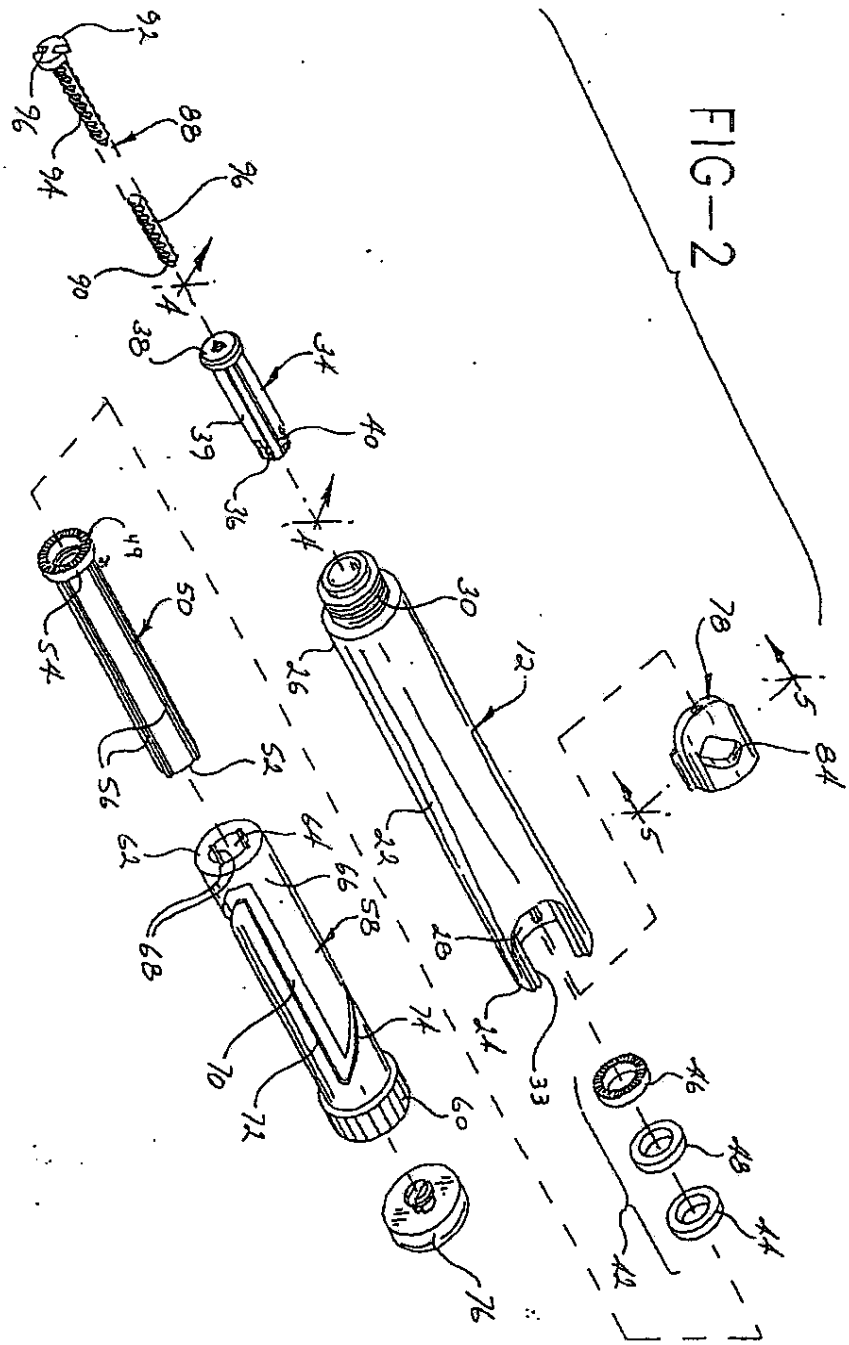
FIG—1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FIG—2

FIG-3

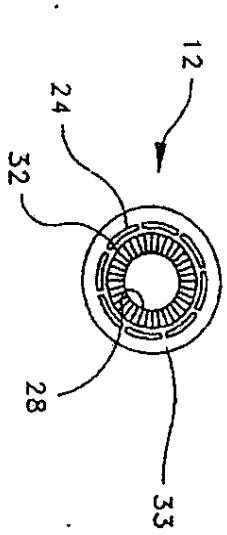


FIG-5

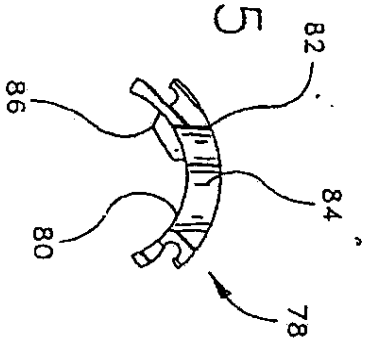


FIG-4

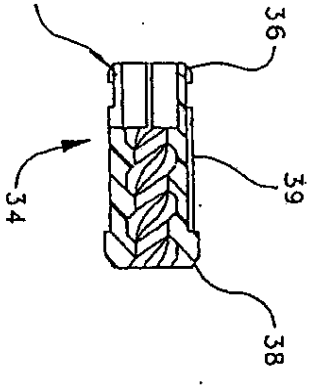
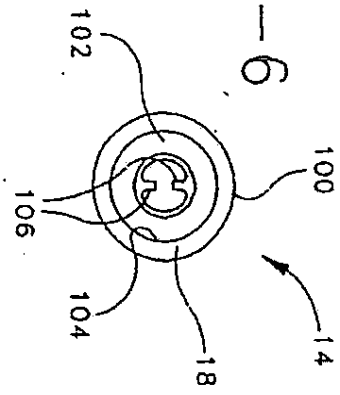
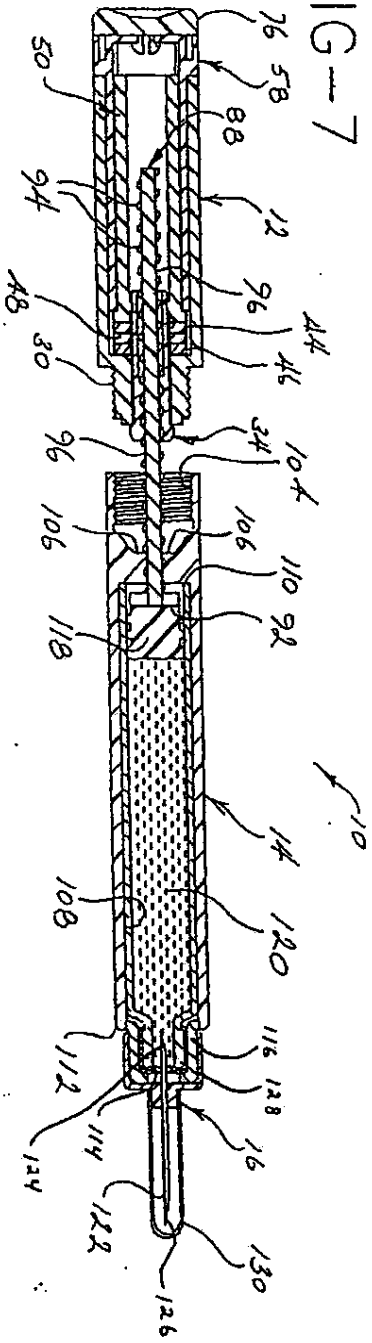


FIG-6



FIG—7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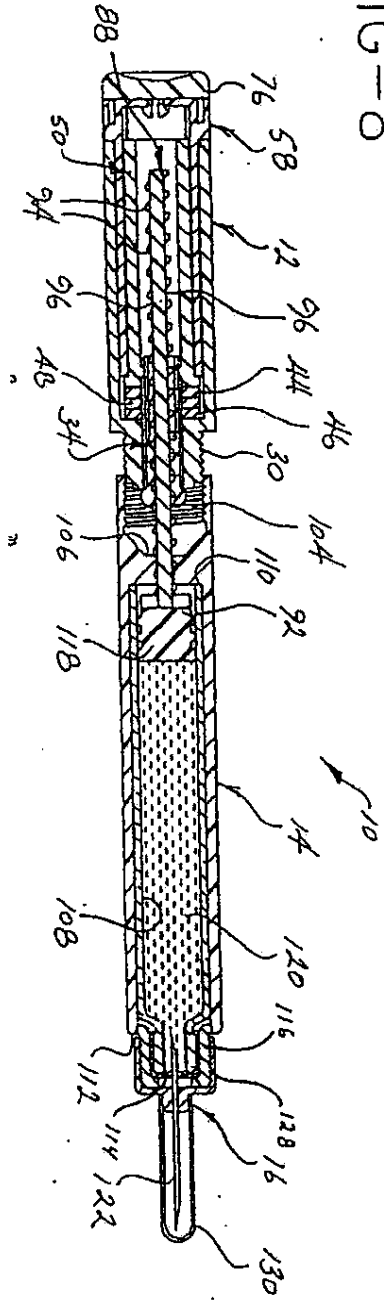
FIG—8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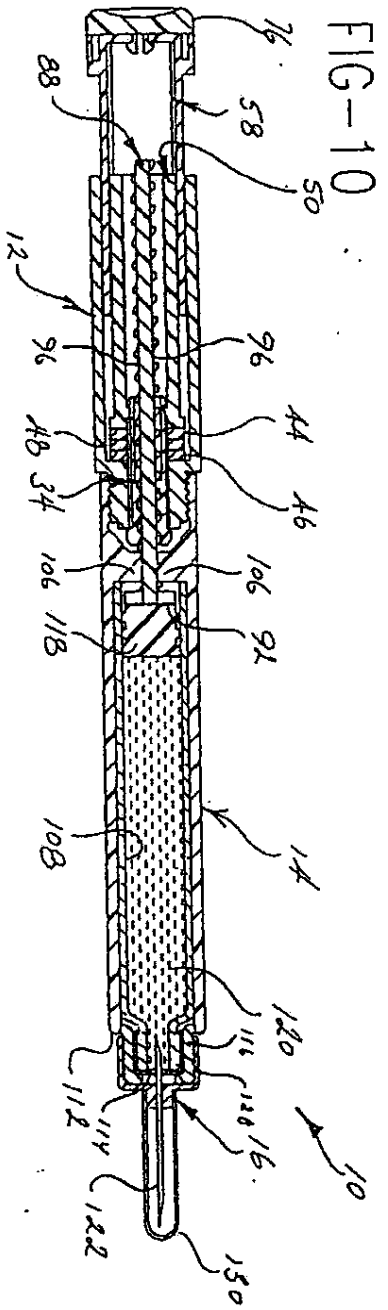
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FIG-10

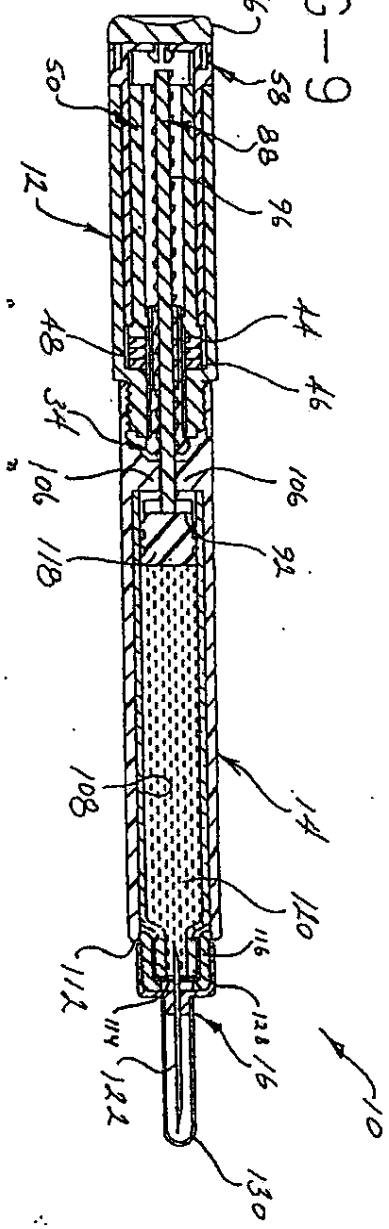
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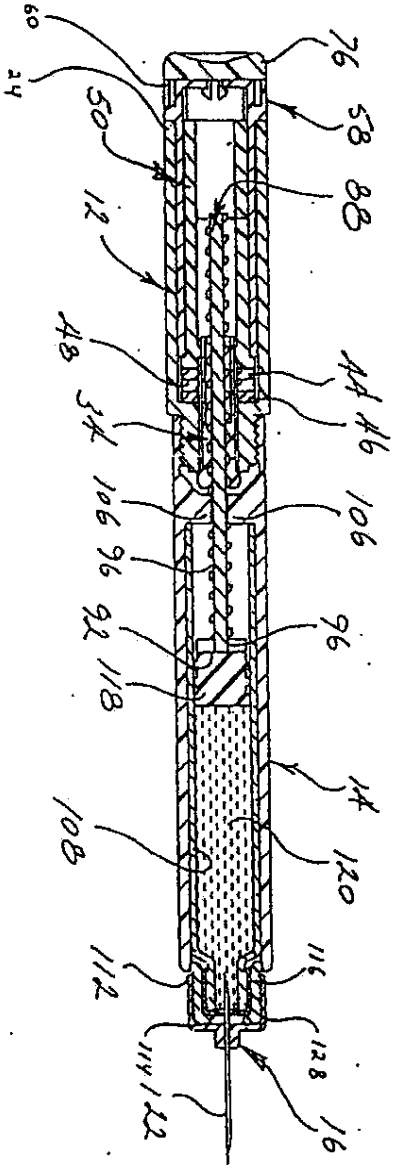
FIG-9

FIG—11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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 30 3894

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X Y	EP-A-0 450 905 (ELI LILLY AND COMPANY) * column 2, line 19 - line 34 * * column 5, line 44 - column 6, line 13; figures 1-3,5,8,9 *	1-3,6-10 5	A61M5/315
Y	EP-A-0 268 191 (WILHELM HASELMEIER GMBH & CO.) * figures 1-4 *	5	
A	US-A-4 973 318 (HOLM ET AL.) * abstract; figures 1-5,13,14,18 *	1-10	
A	EP-A-0 554 995 (BECTON DICKINSON AND COMPANY)		
			TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	20 September 1995	Michels, N

CATEGORY OF CITED DOCUMENTS

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(51) International Patent Classification 6 : A61M 5/24

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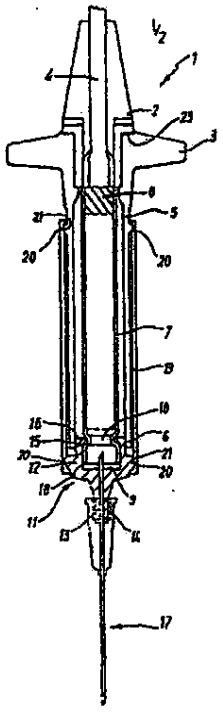
(57) Abstract

A syringe has a drug-containing cartridge (7) with a bung (8) at one end which is engaged by a plunger (4), and a membrane (9) at its other end which is penetrated by a needle. A connecting structure (11) is connected to (or is formed integrally with) the needle (17) and fits onto the forward end of the cartridge (7) and the syringe. After use the cartridge (7), the connecting structure (11) and the needle (17) can be disposed together. A sleeve (19) is slidably mounted on the structure (11) and can be moved to sheath the needle (17).



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SYRINGES

This invention relates to syringes.

A conventional syringe, e.g. as used by a dentist to administer anaesthetic, has a barrel with a plunger mechanism at one end and a threaded connector for a needle at the opposite end. A drug-containing glass cartridge is inserted into the barrel, the needle is screwed onto the connector so that it penetrates a seal at the forward end of the cartridge, and the plunger mechanism is operated to engage a bung at the rearward end of the cartridge and thereby expel the drug through the needle. After use, the needle and cartridge are removed and discarded.

In order to minimise contamination problems, European Application EP 0394295-A describes a syringe in which, in place of the above mentioned cartridge, there is a drug-containing housing which is attached directly to the needle at one end and to the plunger mechanism at the other end. After use the entire housing, including the needle, is detached from the plunger mechanism and discarded thereby avoiding the need to sterilise the barrel and needle connector of the conventional syringe.

Whilst this arrangement provides an effective solution to contamination problems, it is necessary for the specially-constructed detachable housing to be pre-filled with the drug which can be inconvenient from a manufacturing point of view.

An object of the present invention is to provide a disposable syringe housing which is convenient to manufacture.

According to one aspect of the invention therefore there is provided a detachable housing for a syringe comprising a drug-containing cartridge having a bung at one end and a penetrable member at the other end, the cartridge being adapted for connection to a needle at the said other end, such that the needle penetrates the penetrable member, and being adapted for connection to a plunger mechanism at the said one end, so that the bung can be moved down the cartridge to expel the drug through the needle, characterised in that the cartridge is provided with at least one separate structure attachable relative thereto, said structure being adapted for the said connection of the cartridge to the needle and providing means for releasable connection to the plunger mechanism, whereby the housing comprising the cartridge, the (or each) said structure, and the needle can be detached from the plunger mechanism for disposal together.

With this arrangement the advantages of disposability can be attained with an arrangement which is particularly simple and convenient to manufacture in so far as it involves the use of a simple drug-containing cartridge which may be of the kind used with conventional syringes.

Most preferably there is one said structure which is attachable to the said other end of the cartridge and which is adapted for connection to the needle and which provides the means for connection to the plunger mechanism.

Thus, and in accordance with a second aspect of the present invention there is provided a structure for attachment to a drug-containing

cartridge of a syringe, which cartridge has a bung at a rearward end and a penetrable membrane at a forward end, said structure being adapted for attachment to a needle and having means for attachment relative to the forward end of the cartridge, and means for attachment to a plunger mechanism.

The means for attachment to the cartridge may comprise a clip or constriction or the like which fits around a neck at the forward end of the cartridge, such neck being a feature of conventional cartridges.

The structure may be formed integrally with the needle or alternatively it may incorporate means for connection to the needle which may comprise a threaded boss or nipple.

The means for attachment to the plunger mechanism may comprise an outer peripheral retaining structure, such as a screw-thread, adapted to mate with a corresponding retaining structure at the end of a barrel extension on the plunger mechanism, which extension fits around the cartridge from the rearward to the forward end thereof.

The barrel extension may have a longitudinally movable sleeve which can be moved forwardly to sheath the needle after use. This sleeve may be removable and disposable with the housing.

If desired, provision may be made for aspiration, or slight suck back with the syringe so that it can be seen if a vein or atery has been penetrated, such penetration being revealed by suck back of blood.

Thus, the said structure may be provided with a spring arrangement